National Women & Infants Health Programme

National Clinical Practice Guideline

Prevention of Early-Onset Group B Streptococcal Disease in Term Infants

INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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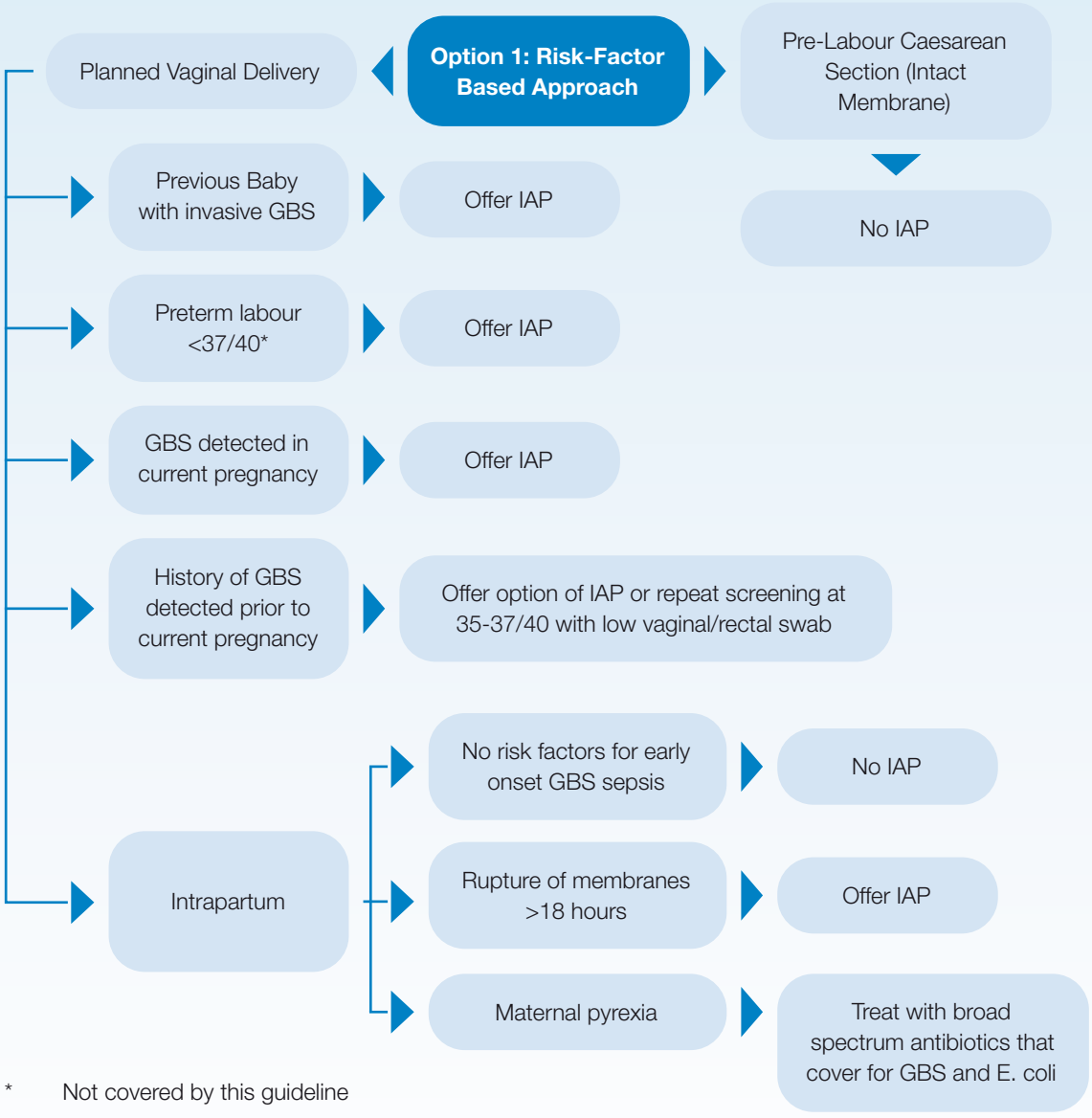

* Not covered by this guideline

GBS group B streptococcus
IAP Intrapartum antibiotic prophylaxis

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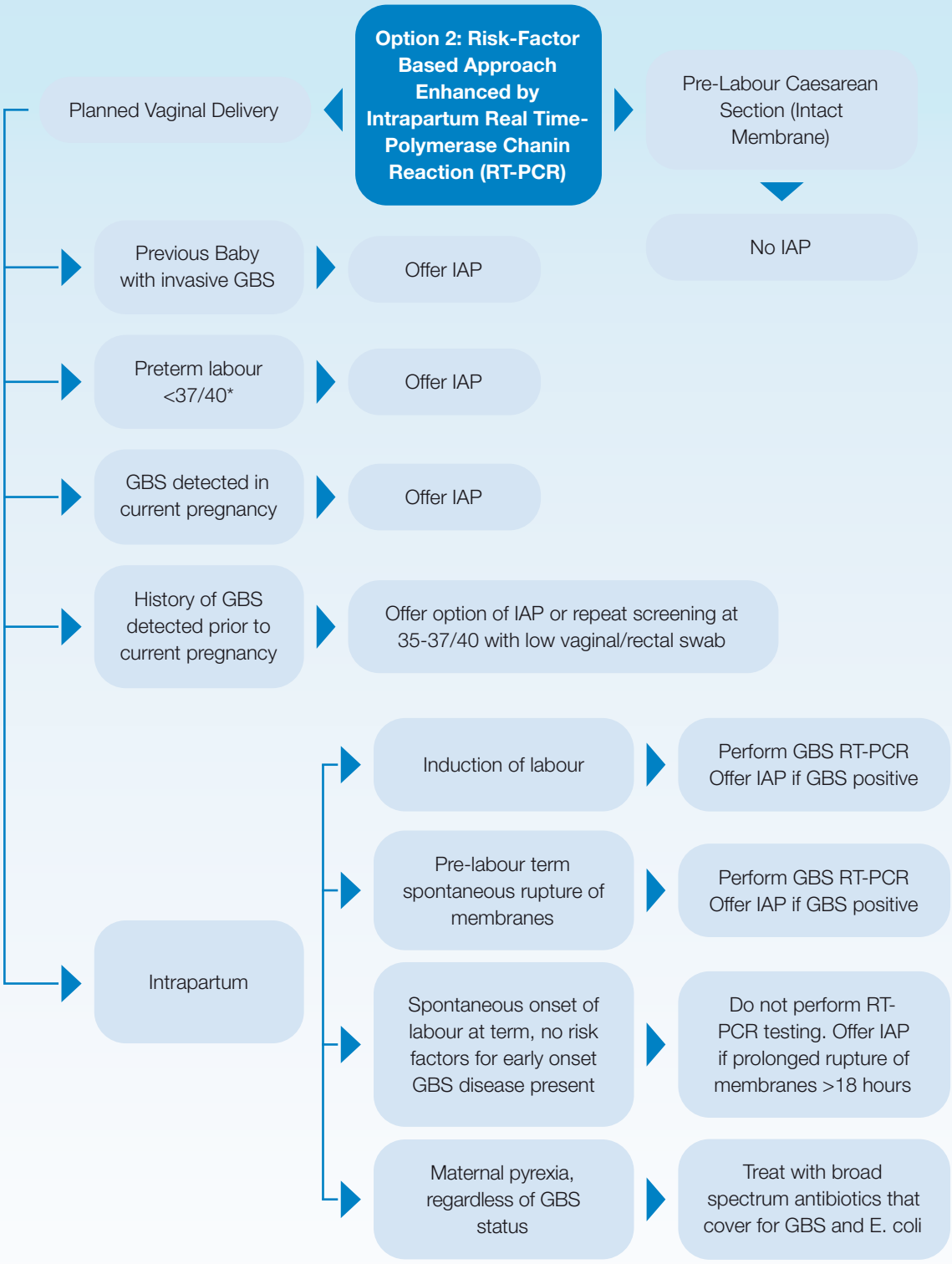

* Not covered by this guideline

GBS group B streptococcus
IAP Intrapartum antibiotic prophylaxis

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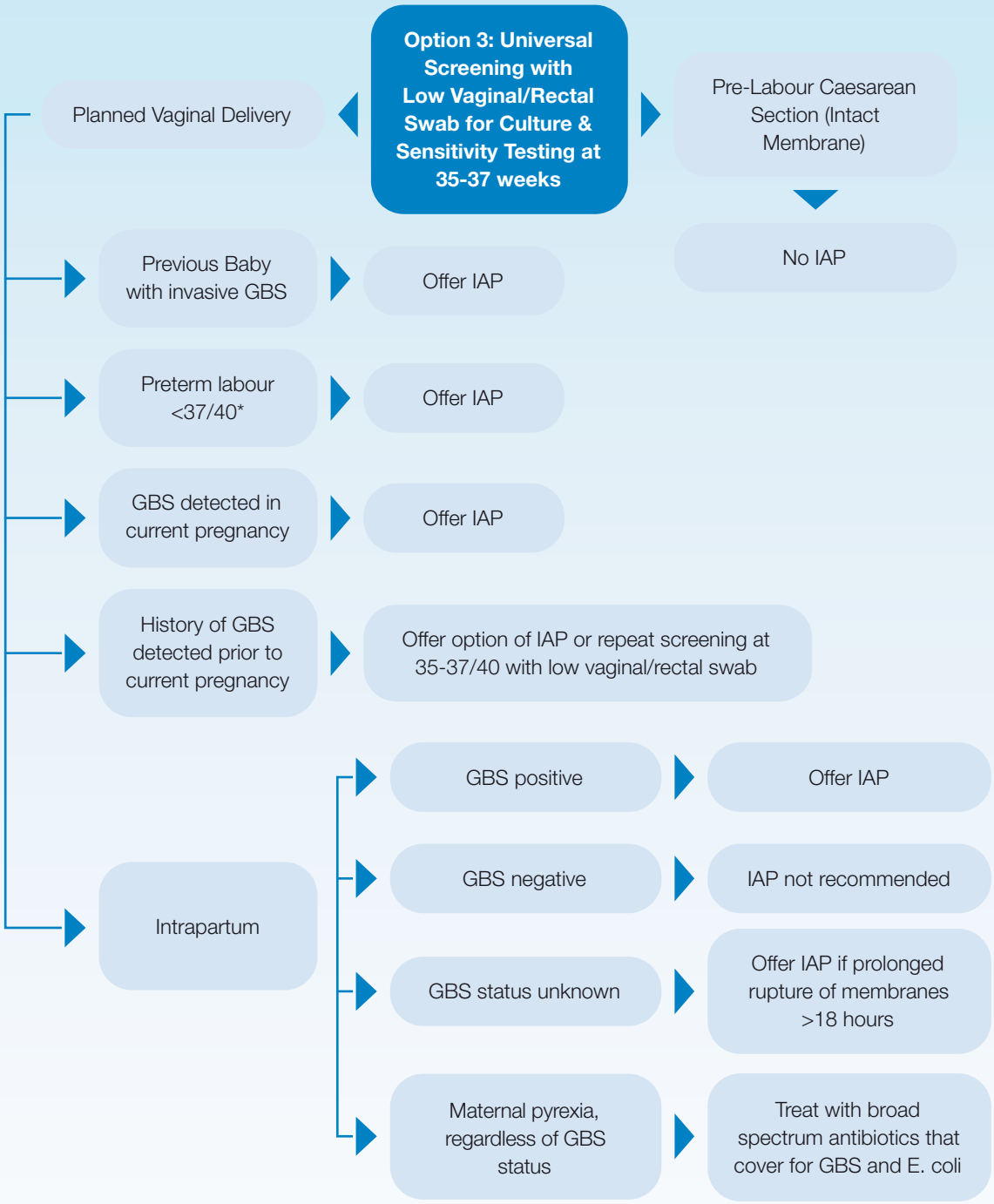

* Not covered by this guideline

GBS group B streptococcus
IAP Intrapartum antibiotic prophylaxis

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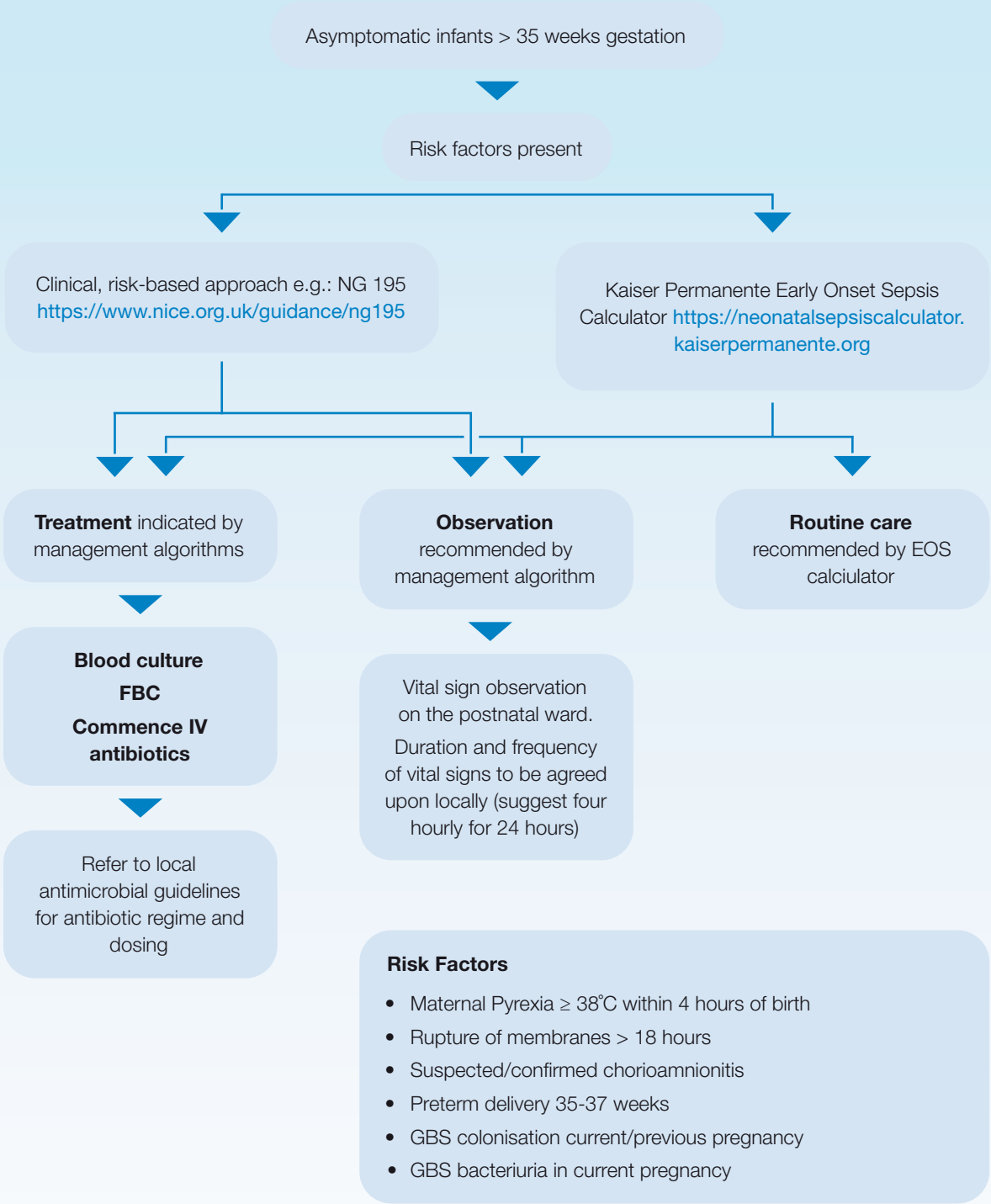

Key Recommendations

Number	Recommendation	Grade
1	We recommend that each maternity unit should choose one of the following GBS screening options: 1. Risk factor-based screening. 2. Risk factor-based screening enhanced by RT-PCR testing of those at highest risk of prolonged ROM (IOL, pre-labour SROM). 3. Universal culture-based screening at 35-37 weeks' gestation.	*1B*
2	We recommend that IAP be offered for GBS bacteriuria of any colony count in the current pregnancy (if appropriate – see clinical question 2.10).	*1B*
3	We recommend that both GBS UTI and asymptomatic GBS bacteriuria of >100,000 CFU requires antenatal treatment.	*1B*
4	We recommend that GBS vaginal colonisation does not require antenatal treatment, but IAP should be offered if appropriate (see clinical question 2.10).	*1C*
5	If a woman has a history of GBS detected before the current pregnancy, we recommend that they should be offered a choice of IAP or repeat GBS screening.	*Best practice*
6	We recommend that if a woman is a known GBS carrier, with pre-labour term SROM, IAP should be offered, and they should be offered induction of labour as soon as reasonably possible.	*1C*
7	We recommend that IAP should be offered in the following circumstances: a. GBS colonisation in current pregnancy (recto-vaginal swab/MSU) or previous GBS colonisation (either during or out with a previous pregnancy) if the women chooses to not be rescreened in the current pregnancy. b. Previous neonatal invasive GBS disease. c. Pyrexia in labour (a single temperature >38ºC). d. Positive intrapartum GBS PCR. e. Prolonged rupture of membranes >18 hours (if GBS status unknown). f. Consider if there is a history of maternal invasive GBS disease.	*1C*
8	We strongly recommend that IV benzylpenicillin is the first line treatment for IAP for people who are not allergic to penicillin. The recommended dosage is 3g IV stat followed by 1.5-1.8g IV every 4 hours until delivery.	*1A*
9	We recommend that IV cefuroxime (1.5g every 6 hours) is the antibiotic of choice for IAP in non-immediate hypersensitivity reaction to penicillin.	*1C*

Number	Recommendation	Grade
10	We suggest that if the history is suggestive of immediate hypersensitivity reaction to penicillin, IV clindamycin (900mg every 8 hours) should be offered if the GBS isolate is known to be clindamycin susceptible. Otherwise, vancomycin should be offered for IAP (15mg/kg every 12 hours, max dose 2g) (Note: Higher vancomycin doses can be used, check with local antimicrobial guidance).	*2C*
11	We recommend that GBS recto-vaginal culture at 35-37 weeks' gestation (for clindamycin susceptibility testing) be considered for people who disclose an immediate hypersensitivity reaction to penicillin.	*Best practice*
12	For intrapartum pyrexia, regardless of GBS status, we recommend commencing broad spectrum IV antibiotics that include coverage for both GBS & E Coli, as per local anti-microbial guidelines.	*1C*
13	We recommend that specific antibiotic prophylaxis for GBS is generally not required for pre-labour Caesarean section where membranes are intact but discussion with neonatology is advised if there is a history of neonatal invasive GBS disease.	*1C*
14	We recommend that maternal cases of confirmed GBS bacteraemia should be managed as per the national maternal sepsis guidelines & national antimicrobial Guideline.	*Best practice*
15	We recommend that GBS colonisation should not be a contraindication to breastfeeding.	*Best practice*
16	We suggest that investigations for a sepsis evaluation in an infant should include a blood culture obtained in a sterile fashion and a full blood count. Lumbar puncture to be considered.	*2A*
17	We suggest that a regime of IV benzylpenicillin and IV gentamicin is usual for EOGBS prophylaxis in infants, refer to local guidelines in maternity unit for information on dosing.	*Best practice*
18	We suggest commencing treatment with IV antibiotics (EOGBS prophylaxis) for any infant who is symptomatic. We also suggest commencing treatment with IV antibiotics for an infant where a sibling in a multiple birth has a positive blood culture. We suggest considering treatment where there is a history of invasive EOGBS in a previous sibling.	*2A*
19	We recommend that each maternity unit should choose and implement one of the following GBS neonatal risk factor management options: A clinical risk-based approach (e.g.: NICE Guideline NG 195) or Kaiser Permanente Early Onset Sepsis Calculator.	*1A*
20	We recommend that care for infants following assessment as per CQ2.18 should comprise either: regular monitoring of vital signs on the postnatal ward; or a sepsis evaluation and IV antibiotics.	*1B*
21	We suggest observing vital signs of the infant on the postnatal ward. Frequency and duration of observations to be agreed locally, we suggest 4 to 6 hourly for a minimum of 24 hours. The overall condition of the infant should be monitored.	*2B*

Number	Recommendation	Grade
22	If a woman has GBS diagnosed on a vaginal swab within the first week of her baby's life, we suggest that the mother be notified of her result, and no further input is warranted if the infant remains well. If GBS UTI is identified on MSU we recommend maternal antibiotic treatment as described above. If the woman has been discharged the positive result can also be shared with her GP.	*Best practice*
23	We recommend that each unit should audit their own incidence rate of EOGBS.	*Best practice*
24	We recommend that laboratories should send GBS isolates from sterile sites to the IMSRL for further analysis and sequencing to help examine national trends. Laboratories should communicate with the IMSRL if the organism was not detected using molecular methods.	*Best practice*

Chapter 1: **Initiation**

The National Clinical Effectiveness Committee (NCEC) and Health Information and Quality Authority (HIQA) define clinical guidelines as systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum[1].

1.1 Purpose

The purpose of this Guideline is to provide a framework to reduce (as far as practicable) prevalence of maternal and neonatal early onset Group B streptococcal (GBS) disease in term infants.

This Guideline is intended to identify the risk factors that may be present in a woman that are associated with the development of early onset GBS (EOGBS) sepsis in an infant. Prophylaxis and/or treatment should be offered where appropriate. These measures, in conjunction with observation and assessment of the infant, will help to prevent early onset disease in infants. The prevention of GBS disease in preterm infants <37 weeks will not be covered by this Guideline. Prevention or management of late onset neonatal GBS is not within the scope of this Guideline, as the prevalence of this is unaffected by peripartum events, screening, or currently available interventions.

1.2 Scope

Target Users

The Guideline is a resource for all clinicians working in hospitals and primary care in Ireland. This includes healthcare staff, Doctors, Midwives, Nurses, health and social care professionals involved in the care of pregnant women and infants.

Target Population

The target populations for this Guideline are:

1. pregnant women who may have risks for peripartum transmission of GBS to their infant
2. infants who may have been exposed to maternal GBS during birth.

1.3 Objective

To provide evidence-based recommendations for the care of women antenatally, during labour and postnatally, and for the assessment and management of infants, to prevent EOGBS disease.

1 National Clinical Effectiveness Committee, Health Information and Quality Authority. National Quality Assurance Criteria for Clinical Guidelines Version 2. Dublin; 2015. https://www.hiqa.ie/sites/default/files/2017-01/National-Quality-Assurance-Criteria.pdf

1.4 Guideline development process

The Guideline Developers agreed to undertake this work under the direction of the Guideline Programme Team (GPT). An Expert Advisory Group (EAG) was commissioned by the GPT. Their role was to critically review the Guideline prior to submission to the National Women and Infants Health Programme (NWIHP) for final approval.

See Appendix 1 for EAG group membership and Appendix 2 for Guideline Programme Process.

The Guideline Developer Group is as follows:

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Dr Mary Meehan, Senior Scientist, Irish Meningitis and Sepsis Reference Laboratory

1.5 Stakeholder involvement

Stakeholders are people who have a common interest in improving health services. This includes persons that are responsible for delivering and those who receive services related to the clinical Guideline.

Group B Strep Support (GBSS) Patient Support Group are a UK-based charity working to eradicate group B streptococcal infection in babies, providing education and support to the public, doctors and midwives, and affected families. This group was consulted in the Guideline development process.

1.6 Disclosure of interests

Guideline developers and reviewers bring a range of experiences and perspectives to the work of the national Guideline Programme. It is likely that both Guideline developers and stakeholders/reviewers will have a variety of interests, arising from different contexts and activities done in a professional or personal capacity. These can include employment and other sources of income, speaking engagements, publications and research, and membership of professional or voluntary organisations. The involvement of individuals with relevant content expertise is essential for enhancing the value of Guideline recommendations, but these individuals may also have interests that can lead to conflicts of interest, as may peer reviewers, patient representatives and researchers.

All interests should be declared if, in the view of a reasonable person, they are relevant, or could be perceived to be relevant, to the work of the clinical practice Guideline in question.[2] Declaring an interest does not mean there is a conflict of interest.

It is important that interests are openly declared so they can be appropriately managed. Conflicts of interest can bias recommendations and ultimately be harmful to patients and the health system. Disclosures of interests and appropriate management of conflicts of interest, when identified, are therefore essential to producing high-quality, credible health guidelines.[3]

The Guidelines International Network (GIN), a global network of Guideline developers that aims to promote best practices in the development of high-quality guidelines, developed a set of 9 principles to provide guidance on how financial and non-financial conflicts of interest should be both disclosed and managed. It is recommended that Guideline developers follow the GIN principles.[4]

For this National Clinical Practice Guideline, all Guideline developers are asked to complete a conflict of interest declaration form. The response to declared interests will be managed by the Guideline programme team, in accordance with GIN principles. Conflicts of interest may be reported in the published Guideline and declarations of interest can be made available.

1.7 Disclaimer

These guidelines have been prepared to promote and facilitate standardisation and consistency of good clinical practice, using a multidisciplinary approach. Information in this Guideline is current at the time of publication.

The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the Clinician in light of clinical data presented by the patient and the diagnostic and treatment options available.

Clinical material offered in this Guideline does not replace or remove clinical judgment or the professional care and duty necessary for each specific woman. Clinical care carried out in accordance with this Guideline should be provided within the context of locally available resources and expertise.

2 NICE (2019) Policy on declaring and managing interests for NICE advisory committees https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/declaration-of-interests-policy.pdf

3 Traversy G, Barnieh L, Akl EA, Allan GM, Brouwers M, Ganache I, Grundy Q, Guyatt GH, Kelsall D, Leng G, Moore A, Persaud N, Schünemann HJ, Straus S, Thombs BD, Rodin R, Tonelli M. CMAJ. 2021, 193(2):E49-E54. DOI: 10.1503/cmaj.200651 https://www.cmaj.ca/content/193/2/E49

4 Holger J. Schünemann, Lubna A. Al-Ansary, Frode Forland, *et al.*; for the Board of Trustees of the Guidelines International Network. Guidelines International Network: Principles for disclosure of interests and management of conflicts in guidelines. Ann Intern Med. 2015;163:548-553. doi:10.7326/M14-1885 https://www.acpjournals.org/doi/10.7326/m14-1885

This Guideline does not address all elements of standard practice and assumes that individual clinicians are responsible for:

- Discussing care with women in an environment that is appropriate and which enables respectful confidential discussion. This includes the use of interpreter services where necessary
- Advising women of their choices and ensure informed consent is obtained
- Provide care with professional scope of practice, meeting all legislative requirements and maintaining standards of professional conduct
- Applying standard precautions and additional precautions, as necessary, when delivering care
- Documenting all care in accordance with local and mandatory requirements.

1.8 Use of language

Within this guidance we use the terms 'woman' and 'women's health'. However, it is important to acknowledge that people who do not identify as cis-gender women are excluded from this descriptor, including people who identify as transgender, gender diverse and gender non-binary[5]. We also appreciate that there are risks to desexing language when describing female reproduction[6,7]. Services and delivery of care must be appropriate, inclusive and sensitive to the needs of people whose gender identity does not align with the sex they were assigned at birth. This includes training and education regarding diverse pathways to pregnancy and the use of practices which affirm the sexual and gender identities of all people using Obstetrics and Gynaecology services.

Language use is key to effectively communicate options, recommendations, and respectfully accept a woman's fully informed decision[8]. With this in mind, the use of birth is preferable to the term delivery in all circumstances and is used consistently where possible throughout the guidelines. It is acknowledged that in some circumstances (e.g., in the case of a medically indicated intervention or surgery) and in some contexts, substituting with the term delivery is considered appropriate and this term may be used instead.

5 Moseson H, Zazanis N, Goldberg E, *et al.* The Imperative for Transgender and Gender Nonbinary Inclusion. Obstet Gynecol. 2020;135(5):1059-1068. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7170432/

6 Brotto LA, Galea LAM. Gender inclusivity in women's health research. BJOG An Int J Obstet Gynaecol [Internet]. 2022 Nov 1 [cited 2022 Oct 19];129(12):1950-2. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.17231

7 Gribble KD, Bewley S, Bartick MC, Mathisen R, Walker S, Gamble J, *et al.* Effective Communication About Pregnancy, Birth, Lactation, Breastfeeding and Newborn Care: The Importance of Sexed Language. Front Glob Women's Heal. 2022 Feb 7;0:3 Accessed June 9, 2022. https://www.frontiersin.org/article/10.3389/fgwh.2022.818856

8 https://blogs.bmj.com/bmj/2018/02/08/humanising-birth-does-the-language-we-use-matter/

Chapter 2:
Clinical Practice Guideline

Background

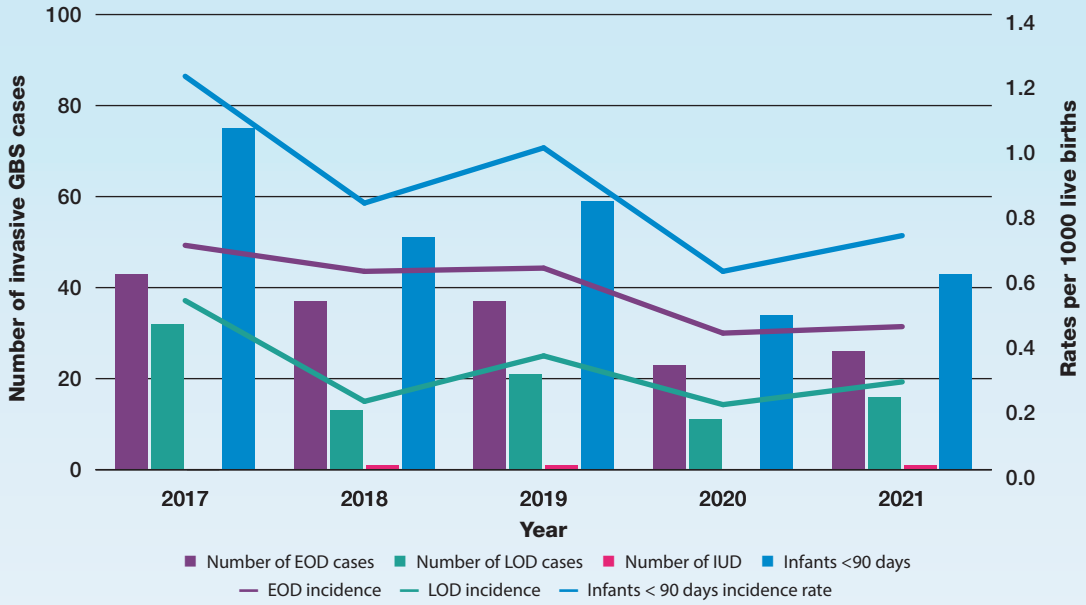
The aim of this Guideline is to provide a framework for reducing early onset neonatal GBS disease (EOGBS). As per the World Health Organisation report in 2021, the global burden of GBS is far higher than previously recognised, linked to over half a million preterm births annually, nearly 100,000 neonatal deaths, at least 46,000 stillbirths, and significant long-term neurodevelopmental (motor and cognitive) impairment [1].

While several GBS vaccine candidates are in development, none are currently available. Introduction of effective vaccination against GBS will be hugely beneficial in terms of prevention of antenatal, early onset, and late onset GBS disease, as well as the consequences of associated maternal infection. In the interim, appropriate triage for intrapartum antibiotic prophylaxis (IAP) is the mainstay of prevention of EOGBS.

Group B Streptococcus (*Streptococcus agalactiae*) is the leading cause of severe early-onset infection in newborn infants. 10-30% of pregnant women are colonised with GBS [2-7]. 36% of babies born to colonised mothers become colonised with GBS at birth, and 1-3% of these babies develop EOGBS bacteraemia [8,9].

Early onset GBS (EOGBS) disease occurs from birth to day six of life, and usually presents with sepsis or pneumonia, whereas late onset GBS disease occurs from day seven to 90 of life, and up to 50% present with meningitis [10,11]. GBS is also associated with an increased risk of preterm birth, endometritis, chorioamnionitis and intrauterine death [11-13]. A number of risk factors are associated with increased perinatal GBS transmission, such as rupture of membranes more than 18 hours before birth, rupture of membranes before the onset of labour, prematurity, and intrapartum fever [14]. Table 1 outlines the incidence of invasive GBS disease in Ireland from 2017 to 2021. [15,16].

Table 1: Incidence of Invasive GBS Cases in Ireland 2017-2021 (Data from Health Protection Surveillance Centre)



There are three strategies for prevention of EOGBS – one of which is a purely risk-based approach, currently used in the United Kingdom, which advises the use of intrapartum antibiotic prophylaxis (IAP) for women who have risk factors for GBS (rupture of membranes >18 hours, intrapartum pyrexia, preterm labour, previous infant with GBS disease and GBS carriage in the current pregnancy) [17]. The United States & Canada perform universal vaginal & rectal culture testing on all pregnant women at 36 to 37+6 weeks' gestation [18,19]. Over 60 countries have a national Guideline for intrapartum antibiotic use to prevent EOGBS – of these, 58% used microbiological screening and 42% used clinical risk factors [20].

A third approach recommends intrapartum GBS polymerase chain reaction (PCR) testing, and antenatal culture at 35-37 weeks' gestation if this is not available [21]. A multicentre randomised controlled trial (GBS3) is currently underway in the UK which is comparing universal screening, risk factor and intrapartum PCR testing and the results of this will likely inform future updates to this Guideline [22].

A review of GBS protocols across the nineteen Irish maternity units highlighted a wide variation in standards for GBS prevention nationally, demonstrated by differing methods used for GBS screening, type of intrapartum antibiotic (IAP) usage, and neonatal management. Two units in Ireland use a risk-factor based approach supplemented by intrapartum PCR screening, and the other units utilise a risk-factor based approach [23].

This Guideline aims to delineate options for screening and prevention of EOGBS, and based on these, each obstetric and neonatal unit is recommended to develop & continually audit a unit policy to ensure that management does not vary within the unit. Units must be aware that screening recommendations may change in time, particularly in the context of ongoing research as described above[22].

There may be circumstances where personal or clinical factors may mandate appropriate deviation from these guidelines. In particular the Guideline Development Group acknowledges that women may have a preference for a particular screening strategy (e.g. routine antenatal screening 35-37 weeks) based on their own experiences. The rationale and impact of this should be discussed and documented in the healthcare record.

Recommendations relevant to this Guideline can also be found in:

- National Clinical Practice Guideline: Induction of labour (due 2023)
- National Clinical Practice Guideline: Vaginal Birth after Caesarean Section[9]
- National Clinical Practice Guideline: Stillbirth – Prevention, Investigation, Management and Care[10]

Section 1: Screening for GBS

Clinical Question 2.1: **What are the options for screening for GBS for EOGBS prevention?**

Evidence Statement

The United States previously recommended either a risk-factor based approach or universal screening via a low vaginal/rectal culture at 35-37 weeks, until a retrospective cohort study comparing the two methods showed that the risk of EOGBS was significantly lower in the universal screening group than among the risk-based group (adjusted relative risk 0.46. 95% confidence interval, 0.36 to 0.60)[24].Thus, the Centre for Disease Control recommended a universal screening-based approach[25]. Updated guidance from the American College of Obstetricians & Gynaecologists (ACOG), American Society of Microbiology (ASM) and American Academy of Paediatrics (AAP) in 2019 changed the recommended timeframe for screening to between 36+0 and 37+6 weeks' gestation [19,26,27]. The Society of Obstetricians & Gynaecologists Canada (SOGC) recommend this approach [18] and the Royal Australian and New Zealand College of Obstetricians & Gynaecologists (RANZCOG) recommend either universal screening or a risk factor-based approach[28]. New Zealand Consensus Guidelines recommend a risk factor-based approach[29].

The incidence of culture confirmed EOGBS in the US has fallen significantly since the introduction of a screening programme, from 1.7 per 1000 live births in 1996 [13], to 0.25 per 1000 live births in 2018 [30]. In the United Kingdom (UK), the Royal College of Obstetricians & Gynaecologists (RCOG) recommends a risk-factor based approach, giving IAP to those with risk factors for EOGBS[17]. The rates of EOGBS disease in the UK & Ireland had historically been lower than in the US, but the incidence of EOGBS in the UK & Ireland has increased from 0.48 in 2000, to 0.57 per 1000 live births in 2015, despite the introduction of the risk-based screening programme in the UK in 2003[31].

A recent meta-analysis showed that universal screening was associated with a reduced risk of EOGBS disease compared with risk-based protocols (RR 0.43, 95% CI 0.32-0.56), and the analysis could not demonstrate a significant effect of risk-based protocols versus no policy (RR 0.86, 95% CI 0.61-1.20). It also showed that screening was not associated with higher antibiotic administration rates (31% vs 29%)[32]. The National Screening Committee in the UK however has recommended against universal screening due to the low incidence of EOGBS sepsis in the UK without screening, the lack of randomised controlled trial evidence assessing the effect of the screening strategies and concern about the safety of intrapartum antibiotic prophylaxis [33]. These concerns are currently being addressed in the context of a large clinical trial [22] which will inform future guidelines.

9 Ryan G, Duggan J, Finnegan C, Morrison JJ. National Clinical Practice Guideline: Vaginal Birth After Caesarean Section. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. January 2023

10 McDonnell A, Butler M, White J, Escañuela Sánchez T, Cullen S, Cotter R, Murphy M, O'Donoghue K. National Clinical Practice Guideline: Stillbirth: Prevention, Investigation, Management and Care. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. January 2023.

The third approach, universal intrapartum PCR testing has been recommended by the European Consensus Conference on intrapartum GBS screening and antibiotic prophylaxis in 2015 [21]. A French study in a unit that has introduced intrapartum GBS PCR testing, assessed the rates of EOGBS pre- and post-introduction of intrapartum PCR testing and showed that the rate of proven early-onset GBS disease cases decreased from 1.01/1,000 to 0.21/1,000, and probable early-onset GBS disease cases from 2.8/1,000 to 0.73/1,000 [34]. A previous study in the same unit showed that GBS PCR had a sensitivity of 98.5%, and specificity of 99.6%, a positive predictive value of 97.8% and negative predictive value of 99.7% when compared to culture, and the positive predictive value of antenatal culture for identifying colonisation status at birth was 58.3% [35].

Several single-centre studies have showed similar sensitivities of self-collection versus physician collection of vaginal/rectal swabs for culture testing in late pregnancy [36-41].

Clinical Practice

There are three possible pathways in terms of triaging for IAP, and a hospital should ensure that local clinical guidance enables operationalising of the chosen pathway/s. Ongoing clinical audit should be performed to ensure safety and efficacy, and institutions should be open to evidence-based change over time.

Missed opportunities for EOGBS prevention will exist in all three care options and lead to preventable infant morbidity, while overtreatment, undesirable in the light of medicalising birth, rising antibiotic resistance and potential effects on the microbiome, may occur too. Intrapartum antibiotic use affects the neonatal microbiome, potentially diminishing beneficial commensals, however, further research is required to evaluate the potential long-term consequences of this[42].

When testing for GBS carrier status a swab should be taken from the lower vagina and the anorectum. A single swab (vagina then anorectum) or two different swabs can be used. The type of swab use will vary depending on whether the proposed test is GBS PCR or GBS culture. This swab should be taken by a healthcare worker, but there is also an option of self-sampling if the woman requests, with appropriate advice.

Option 1:

- Risk-factor based screening
    - Provision of IAP for women with specific risk factors for EOGBS including:
        - Prolonged rupture of membranes (ROM) >18h
        - Previous infant with invasive GBS disease
        - GBS detected in the current pregnancy
            - Or GBS detected prior to the current pregnancy, if the woman does not choose rescreening for GBS
        - Maternal pyrexia.

Option 2:

- Real Time-PCR screening at induction of labour or prelabour term – spontaneous rupture of membranes (SROM)
    - This is risk-factor based screening enhanced by PCR testing of those at highest risk of prolonged rupture of membranes.

Option 3:

- Routine universal antenatal screening at 35-37 weeks' gestation
    - Bacteriological culture testing using a combined low vaginal & rectal swab.

The management options are outlined in algorithms 1, 2 and 3. Also see appendix 3 for an outline of the strengths & limitations of each option.

Recommendations

1. **We recommend that each maternity unit should choose and implement one of the following GBS screening options:**
    - A. **Risk factor-based screening.**
    - B. **Risk factor-based screening enhanced by RT-PCR testing of those at highest risk of prolonged ROM (IOL, pre-labour SROM).**
    - C. **Universal culture-based screening at 35-37 weeks' gestation.**

In view of GBS resistance profile to non-penicillin drugs, routine GBS culture & sensitivity can also be considered for all pregnant women with a history of significant penicillin allergy (see clinical question 2.8).

Section 2: Antenatal Care

Clinical Question 2.2: **How should a woman with GBS bacteriuria in the current pregnancy be cared for?**

Evidence Statement

The current ACOG & SOGC guidelines recommend antenatal treatment of symptomatic GBS bacteriuria of any colony count, and asymptomatic GBS bacteriuria with a colony count of $>10^5$ colony-forming units, as it decreases the risk of pyelonephritis, preterm birth & low birth weight infants [19,43]. The RCOG recommends antenatal treatment of GBS bacteriuria of $>10^5$ colony-forming units [17]. A Cochrane review in 2017 found that antibiotic treatment for asymptomatic bacteriuria has been shown to reduce the risk of pyelonephritis (RR 0.23; 95% CI 0.13 to 0.41) and low birth weight (RR 0.66; 95% CI 0.49-0.89), with a reduction in the rate of preterm birth noted but due to the small number of studies included, it could not draw a significant conclusion on this [44]. A systematic review in 2017 found that preterm birth was associated with GBS bacteriuria in the current pregnancy (RR 1.98; 95% CI 1.45-2.69) [12]. Antenatal antibiotics should be prescribed as per the National Antimicrobial Prescribing Guideline [45].

International guidance also recommends that if GBS bacteriuria of any colony count is detected antenatally, IAP should be offered in labour and the woman should not be rescreened for GBS [17,19,28,43]. GBS bacteriuria, of any colony count, confers a 5.6-fold increased risk of intrapartum GBS colonisation [46].

In the case of penicillin allergy, clindamycin susceptibility testing should be performed on the urine sample [28].

Clinical Practice

Asymptomatic GBS bacteriuria of greater than 100,000 colony forming units should be treated with antibiotics.

A woman symptomatic of a GBS urinary tract infection should be treated with antibiotics.

If GBS bacteriuria of any colony count is found in the current pregnancy, then the woman should be informed and should be offered IAP (if appropriate[1]) and not routinely offered repeat GBS screening.

In the case of penicillin allergy, clindamycin susceptibility testing should be performed on the urine sample.

Clinical Question 2.3: **What care should be given to a woman with antenatal vaginal GBS colonisation?**

Evidence Statement

Routine antenatal treatment of GBS vaginal colonisation is not advised as it is associated with a 67% rate of recurrence later in the pregnancy [17,28,47]. IAP should be offered [17]. A systematic review which included nine studies showed that antenatal GBS colonisation was associated with a significant increased risk of colonisation during labour, and there was a 39% risk of intrapartum colonisation if a positive swab was taken at conception (p=0.001), and this risk increased by 1.1% per week of gestation closer to term at which the swab was taken [8].

Clinical Practice

GBS vaginal colonisation in the antenatal period does not need treatment.

If GBS is detected on a vaginal swab at any stage during pregnancy, this should be recorded in the patient record, the woman should be informed and should be offered IAP from the start of labour and at intervals until birth (if appropriate). IAP to reduce EOGBS is not generally required in the setting of elective pre-labour Caesarean birth with intact membranes ; refer to clinical question 2.10. In this situation, some women may request rescreening at 35-37 weeks' gestation, this should be discussed on an individual basis.

Clinical Question 2.4: **What care should be given to a pregnant woman with a previous history of GBS colonisation or infection?**

Evidence Statement

A meta-analysis in 2015 evaluated the risk of recurrence of GBS colonisation. It included three retrospective cohort studies and found that there was a 50% likelihood of recurrence of GBS colonisation in a subsequent pregnancy, compared to a 14% chance of GBS if no prior history of colonisation in the previous pregnancy (pooled fixed effects OR 6.05, CI 4.84-7.55) [48]. International guidelines recommend that a woman should be offered the choice of IAP, or rescreening for GBS [17,19,29]. If there is a history of invasive GBS disease, then a woman should receive IAP [17-19].

There is insufficient evidence to make a formal recommendation on care for a woman with a history of GBS colonisation or infection prior to the current pregnancy (either in a previous pregnancy or outside of pregnancy)

Clinical Practice

Women should be informed about the 50% risk of recurrence of GBS colonisation in a subsequent pregnancy. Provided there is no additional indication for IAP (e.g. previous infant with invasive GBS disease), they should be offered the choice of either antenatal screening for GBS at 35-37 weeks' gestation or IAP.

If there is a history of GBS colonisation or infection outside of pregnancy, inform the woman that there is insufficient evidence regarding recommendations in this scenario. She can be offered the choice of IAP or repeat GBS screening.

Recommendations

2. **We recommend that IAP be offered for GBS bacteriuria of any colony count in the current pregnancy (if appropriate – see clinical question 2.10).**
3. **We recommend that both a GBS UTI and asymptomatic GBS bacteriuria of >100,000 CFU requires antenatal treatment.**
4. **We recommend that GBS vaginal colonisation does not require antenatal treatment, but IAP may be offered if appropriate (see clinical question 2.10).**
5. **If a woman has had GBS detected before the current pregnancy, we recommend that they should be offered a choice of IAP or repeat GBS screening.**

Section 3: Intrapartum Care

Clinical Question 2.5: **How should a woman who is a known GBS carrier be cared for in labour?**

Evidence Statement

A randomised controlled trial by Boyer & Gotoff showed that the use of intrapartum antibiotics reduced the rates of both neonatal GBS colonisation and early-onset GBS disease [49]. A subsequent systematic review showed a 30-fold reduction (95% CI 0.0013-0.17) in EOGBS with IAP [50]. A Cochrane review in 2014 suggested that IAP resulted in a reduction in incidence of both confirmed EOGBS disease (RR 0.17, 95% CI 0.04-0.17, number needed to benefit 25), and probable EOGBS (RR 0.17, 95% CI 0.03-0.91; number needed to benefit 20), but no statistically significant reduction in the risk of neonatal all-cause mortality or GBS-specific mortality, and no effect on LOGBS [51]. However, the authors comment that the trials included were poor quality and had a high risk of bias.

The RCOG, ACOG, RANZCOG, SOGC and the Intrapartum GBS Screening and antibiotic prophylaxis: a European Consensus Conference recommend IAP for women who are known GBS carriers [17-19,21,25].

Maternal GBS carriage is an independent predictor of definite or probable neonatal infection (OR 3.08, 95% CI 2.02-4.68) [52]. A further analysis of this study cohort compared induction with oxytocin, induction with prostaglandin or expectant management and showed that for women who were GBS carriers, the rates of neonatal infection were 2.5% for the induction with oxytocin group and >8% for the other groups, concluding that induction of labour with oxytocin many be preferable for women who have pre-labour term rupture of membranes and are colonised with GBS [53]. International guidance recommends induction of labour for women who have pre-labour term rupture of membranes and are GBS carriers [17-19,21,29,54].

Clinical Practice

Women who test GBS positive on either real-time PCR or antenatal recto-vaginal or urine culture testing should be offered IAP, if appropriate[1], at the onset of labour or as soon as possible after rupture of membranes.

In the case of pre-labour rupture of membranes at term, IAP should be offered, and induction of labour should be offered as soon as reasonably possible.

Clinical Question 2.6: **How should a history of maternal or neonatal invasive GBS disease be managed?**

Evidence Statement

International consensus is that women with a history of neonatal invasive GBS disease in their babies should be offered IAP in subsequent pregnancies [17-19,21,28,29].

Clinical Practice

IAP should be offered to women with a history of neonatal invasive GBS disease and they should not be routinely screened for GBS.

Clinical Question 2.7: **What are the indications for IAP for prevention of EOGBS in term infants?**

There is an absence of evidence pertaining to the risk of EOGBS in subsequent pregnancies in women who previously have a personal history of invasive GBS disease (sterile site infection e.g. pyelonephritis) IAP should also be offered as an option for these pregnant women.

Evidence Statement

Supporting evidence for the following indications for IAP are previously outlined in sections 1, 2 and 3.

Clinical Practice

These are the following indications for offering IAP:

1. GBS detected in current pregnancy, or prior to or during a previous pregnancy if the woman chooses to not be rescreened in the current pregnancy
2. Previous neonatal invasive GBS disease
3. Pyrexia in labour
4. Positive intrapartum GBS PCR test (If GBS negative on intrapartum PCR or antenatal culture, there is an absence of evidence as to the most appropriate timing of IAP in the setting of prolonged rupture of membranes. Consider IAP at 48 hours following SROM for such women)
5. Prolonged rupture of membranes >18 hours (if GBS status unknown)
6. Consider IAP if there is a history of maternal invasive GBS disease.

Even if the above criteria are met, IAP is generally not indicated in the context of pre-labour Caesarean birth with intact membranes. See clinical question 2.10.

The provision of IAP in preterm labour is not covered by this Guideline.

Clinical Question 2.8: **What antibiotics should be used for the prevention of EOGBS?**

Evidence Statement

The National Medication Prescribing Guidelines for Obstetrics & Gynaecology should be referred to for choice of antibiotics [45]. Benzylpenicillin is the agent of choice internationally for IAP [17-19,21,28,29]**.** A Cochrane review stated that amoxicillin was equally as effective for the prevention of EOGBS but that benzylpenicillin was preferred as this has a narrower spectrum of action [51].

A cephalosporin is the recommended antibiotic for non-immediate penicillin allergy [17-19].

The RCOG recommends vancomycin for immediate hypersensitivity reaction to penicillin, due to high rates of clindamycin resistance in the UK [17]. Other countries recommend clindamycin if the GBS isolate is known to be sensitive to clindamycin [18,19,21,28].

The European Consensus Conference on Intrapartum GBS Screening and Antibiotic Prophylaxis recommended recto-vaginal culture & sensitivity testing at 35-37 weeks' gestation for those at risk of severe penicillin allergy, to perform clindamycin susceptibility testing [21]. Antenatal penicillin allergy testing is also an option, to confirm true penicillin allergy. A recent study of pregnant women in the US found that 93% of the patients with reported penicillin allergy had negative penicillin allergy testing and were de-labelled as penicillin allergic. Almost 20% of these were subsequently GBS positive and required IAP, and were therefore able to be offered first-line antibiotic prophylaxis [55]. This approach is recommended by the ACOG [19].

Clinical Practice

Antibiotics should be offered as per the National Antimicrobial Prescribing Guidelines[45].

IV benzylpenicillin is the recommended first line treatment, as outlined in Table 2. Benzylpenicillin 3g IV should be given at the onset of labour, followed by 1.5-1.8g IV every 4 hours until delivery.

In the case of penicillin allergy, clarify the type of reaction with detailed history-taking. If the history suggests non-immediate hypersensitivity reaction cefuroxime is currently recommended, at a dose of 1.5g IV every 6 hours from the onset of labour until delivery. Clindamycin 900mg IV every 8 hours can be used as an alternative if the isolate is known to be sensitive to clindamycin.

Offer clindamycin for a history suggestive of immediate hypersensitivity reaction, if the GBS isolate is known to be sensitive to clindamycin. Otherwise, vancomycin should be offered for IAP (15mg/kg every 12 hours, max dose 2g) (Note: Higher vancomycin doses can be used, check with local antimicrobial guidance). Table 3 outlines clindamycin resistance rates in Ireland from 2017 to 2021.

For this reason, it may be appropriate to routinely offer GBS culture testing at 35-37 weeks gestation for clindamycin susceptibility testing for people who are penicillin allergic.

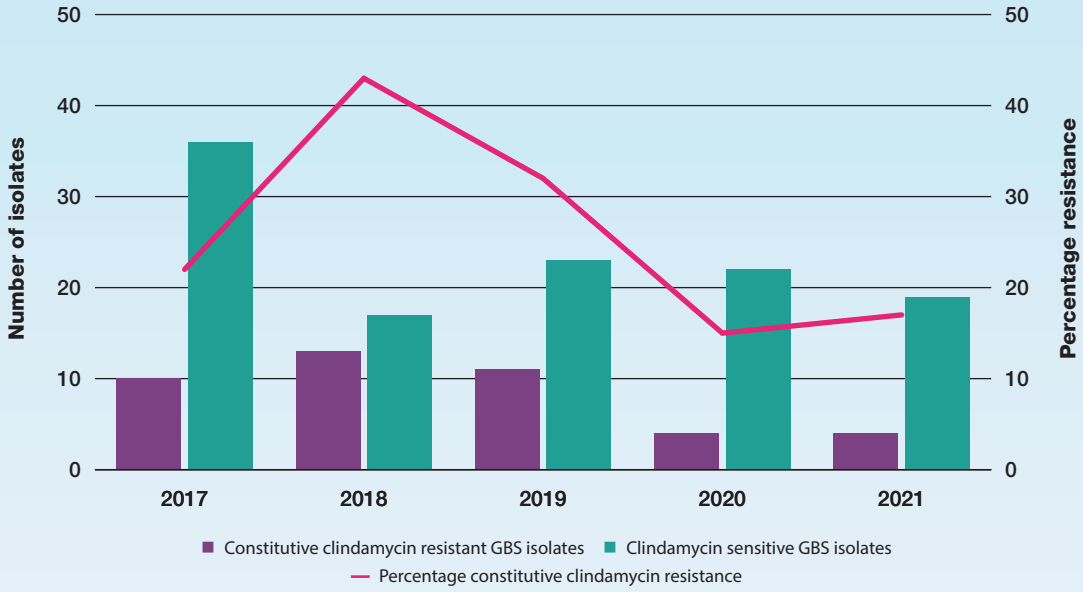
Antenatal penicillin skin allergy testing is an adjunctive option for this cohort of patients if resources are available.

Table 2: Intrapartum antimicrobial prophylaxis (replicated from Medications Guidelines for Obstetrics & Gynaecology – volume 1: Antimicrobial Prescribing Guidelines) 45

Prophylaxis	No penicillin allergy	Non-immediate penicillin allergy	Severe or immediate penicillin allergy	Notes
Intrapartum antimicrobial prophylaxis for the reduction of early-onset invasive group B Streptococcal disease in the neonate	**Option 1:** Benzylpenicillin 3g stat then 1.5-1.8g QDS IV	**Option 1:** Cefuroxime 1.5g QDS IV **Option 2:** Clindamycin 900mg TDS IV **Option 3:** *Vancomycin 15mg/kg BD (max 2g/dose) The choice between option 2 and 3 depends on the susceptibility of Group B Streptococcus to clindamycin	**Option 1:** Clindamycin 900mg TDS IV **Option 2:** *Vancomycin 15mg/kg BD (max 2g/dose) depending on GBS susceptibility The choice between option 1 and 2 depends on the susceptibility of Group B Streptococcus to clindamycin	If the mother herself is septic or pyrexial this section is not suitable. See section on intrapartum pyrexia or chorioamnionitis. The treatment should continue until the woman has delivered. For advice regarding which women require intrapartum prophylaxis see local guidelines.

* Higher vancomycin doses can be used, check with local antimicrobial guidance

Table 3: Clindamycin Resistance Rates from Invasive GBS Isolates in Ireland 2017-2021 (Data from Health Protection Surveillance Centre)



Clinical Question 2.9: **What is the recommended management of intrapartum pyrexia (>38°C) with or without known GBS colonisation?**

Evidence Statement

RCOG defines pyrexia in labour as a single temperature >38°C. [17] Pyrexia in labour increases the risk of EOGBS to 5.3 per 1000 live births, from a background risk of 0.6 per 1000 live births [14]. Refer to the National Sepsis Guideline when caring for these women [56]. The choice of antibiotics should be made according to the National Antimicrobial Prescribing Guidelines [45].

Clinical Practice

If a woman has an intrapartum pyrexia, regardless of GBS status, care should be provided in line with the IMEWS Escalation Policy and National Sepsis Pathway for Maternity Patients. This includes intravenous administration of broad-spectrum antibiotics that include coverage for both GBS and E. coli. Table 4 outlines the antibiotic choice for intrapartum pyrexia based on the National Antimicrobial Prescribing Guidelines [45].

Table 4: Management of Intrapartum Pyrexia (replicated from Medications Guidelines for Obstetrics & Gynaecology – volume 1: Antimicrobial Prescribing Guidelines)[45]

Antenatal Infection	No penicillin allergy	Non-immediate penicillin allergy	Severe or immediate penicillin allergy	Notes
Intrapartum pyrexia	**Option 1:** Benzylpenicillin 3g stat then 2.4g QDS IV AND Gentamicin 5mg/kg/day IV (max 480mg/day) in either one single dose or in 3 divided doses AND Metronidazole 500mg TDS IV **Option 2:** Cefuroxime 1.5g QDS IV AND Gentamicin 5mg/kg/day IV (max 480mg/day) in either one single dose of in 3 divided doses AND Metronidazole 500mg TDS IV **Option 3:** Co-amoxiclav 1.2g TDS IV AND Gentamicin 5mg/kg/day IV (max 480mg/day) in either one single dose or in 3 divided doses	**Option 1:** Cefuroxime 1.5g QDS IV AND Gentamicin 5mg/kg/day IV (max 480mg/day) in either one single dose of in 3 divided doses AND Metronidazole 500mg TDS IV **Option 2:** Clindamycin 900mg TDS IV AND Gentamicin 5mg/kg/day IV (max 480mg/day) in either one single dose of in 3 divided doses **Option 3:** *Vancomycin 15mg/kg BD (max 2g/dose) depending on GBS susceptibility AND Gentamicin 5mg/kg/day IV (max 480mg/day) in either one single dose of in 3 divided doses AND Metronidazole 500mg TDS IV The choice between option 2 and 3 depends on the susceptibility of Group B Streptococcus to clindamycin	**Option 1:** Clindamycin 900mg TDS IV AND Gentamicin 5mg/kg/day IV (max 480mg/day) in either one single dose of in 3 divided doses **Option 2:** *Vancomycin 15mg/kg BD (max 2g/dose) AND Gentamicin 5mg/kg/day IV (max 480mg/day) in either one single dose or in 3 divided doses AND Metronidazole 500mg TDS IV The choice between option 1 and 2 depends on the susceptibility of Group B Streptococcus to clindamycin	It is important that the susceptibility of any previously grown Group B Streptococcus is checked prior to choosing the antimicrobial regimen. The neonatal team should be informed of cases of intrapartum pyrexia so that they can assess the baby. Institutions should monitor their rate of erythromycin/clindamycin resistance amongst Group B Streptococcal isolates to determine if it is reasonable to use clindamycin empirically.

* Higher vancomycin doses can be used, check with local antimicrobial guidance

Clinical Question 2.10: **Do women who are colonised with GBS undergoing elective Caesarean section require antibiotic prophylaxis?**

Evidence Statement

Specific antibiotic prophylaxis against GBS is not required in this scenario [17-19,28,29]. Broad spectrum antibiotic prophylaxis should be offered to all women undergoing Caesarean birth in accordance with the NICE Guideline on Caesarean Birth and the National Antimicrobial Prescribing Guidelines [45,57].

Clinical Practice

Specific antibiotic prophylaxis for GBS is generally not required for pre-labour Caesarean births in the setting of intact membranes.

An exception to this may be the scenario where a woman having a pre-labour Caesarean birth has a history of invasive neonatal GBS disease. Discussion with neonatology is prudent regarding IAP, septic workup and whether there is a need for antibiotic prophylaxis in the infant (see clinical question 17). Similarly, although there is no specific evidence in this regard, a woman who has had previous invasive GBS infection herself may also warrant intravenous antibiotic prophylaxis.

Recommendations

6. We recommend that if a woman is a known GBS carrier, with pre-labour term SROM, IAP should be offered, and they should be offered induction of labour as soon as reasonably possible.
7. We recommend that IAP should be offered in the following circumstances:
    a. GBS colonisation in current pregnancy (recto-vaginal swab/MSU) or previous GBS colonisation (either during or out with a previous pregnancy) if the woman chooses to not be rescreened in the current pregnancy.
    b. Previous neonatal invasive GBS disease.
    c. Pyrexia in labour (>38°C).
    d. Positive intrapartum GBS PCR.
    e. Prolonged rupture of membranes >18 hours (if GBS status unknown).
    f. Consider if there is a history of maternal invasive GBS disease.
8. We strongly recommend that IV benzylpenicillin is the first line treatment for IAP for women who are not allergic to penicillin. The recommended dosage is 3g IV stat followed by 1.5-1.8g IV every 4 hours until delivery.
9. We recommend that IV cefuroxime (1.5g every 6 hours) is the antibiotic of choice for IAP in non-immediate hypersensitivity reaction to penicillin.
10. We suggest that if the history is suggestive of immediate hypersensitivity reaction to penicillin, IV clindamycin (900mg every 8 hours) should be given if the GBS isolate is known to be susceptible. Otherwise, vancomycin should be offered for IAP (15mg/kg every 12 hours, max dose 2g) (Note: Higher vancomycin doses can be used, check with local antimicrobial guidance).
11. We recommend that GBS recto-vaginal culture at 35-37 weeks' gestation (for clindamycin susceptibility testing) be considered for people who disclose an immediate hypersensitivity reaction to penicillin.
12. For intrapartum pyrexia, regardless of GBS status, we recommend commencing broad spectrum IV antibiotics that include coverage for both GBS & E Coli, as per local antimicrobial guidelines.
13. We recommend that specific antibiotic prophylaxis for GBS is generally not required for pre-labour Caesarean section in the setting of intact membranes, but discussion with neonatology is advised in the case of a history of invasive GBS disease.

Section 4: Postnatal Care

Clinical Question 2.11: **What is the recommended postpartum care for mothers with confirmed GBS bacteraemia?**

Evidence Statement

Women with GBS bacteraemia should be cared for in accordance with the National Sepsis Guidelines and National Antimicrobial Guidelines [45,56].

Clinical Practice

Once GBS has been confirmed in the blood culture, then the antimicrobial regimen should be narrowed as much as possible to benzylpenicillin monotherapy (if no penicillin allergy present, and if no other pathogens identified). Treatment should be in line with the National Sepsis Guideline. Aim to switch to oral antibiotics once 24-48 hours afebrile. Treatment can be completed with oral amoxicillin. The total duration of IV and oral antibiotics is usually 7-10 days, but the final decision on duration depends on complications (i.e. meningitis, endocarditis), the woman's clinical status and response to treatment.

The woman should be advised that she will be offered the option of GBS testing or IAP in her next pregnancy (see clinical question 2.6)

The neonatology team should be immediately informed if a woman develops perinatal GBS bacteraemia (see clinical question 2.17).

Clinical Question 2.12: **Is GBS colonisation a contraindication to breastfeeding?**

Evidence Statement

There is no evidence to discourage breastfeeding in women colonised with GBS. [17]

Clinical Practice

Women should be reassured that GBS colonisation is not a contraindication to breastfeeding, and they should be offered support regarding same.

Recommendations

14. **We recommend that maternal cases of confirmed GBS bacteraemia should be managed as per the maternal national sepsis guidelines & national antimicrobial Guideline.**
15. **We recommend that GBS colonisation should not be a contraindication to breastfeeding.**

Section 5: Paediatric Management

Clinical Question 2.13: **What are the risk factors for the development of EOGBS disease in infants?**

Evidence Statement

Good quality evidence from a systematic review including data from RCTs and observational studies shows that the use of IAP decreases colonisation and subsequent risk of early onset GBS disease in infants. [9] Moderate quality evidence of risk factors associated with invasive disease are available from epidemiological studies and published literature reviews (maternal GBS culture positive at delivery (OR: 204), PROM >18 hours (OR: 7.28), intrapartum fever >37.5°C (OR: 4.05), intrapartum fever or PROM at term (OR: 11.5), chorioamnionitis (OR: 6.43). Histological chorioamnionitis is associated with neonatal infection. [58-60]

Clinical Practice

Risk factors associated with EOGBS disease that should be observed for include:

- Maternal Pyrexia ≥ 38ºC within 4 hours of birth
- Rupture of membranes > 18 hours
- Suspected/confirmed chorioamnionitis
- Preterm delivery < 37 weeks
- GBS colonisation current/previous pregnancy
- GBS bacteriuria in current pregnancy.

Clinical Question 2.14: **What are the risk factors for the development of EOGBS disease in infants?**

Evidence Statement

Clinical signs and symptoms are well described in the literature and though all are indicators of an unwell infant, no sign or signs is/are specific for early onset disease [61]. Moderate quality evidence from prospective cohort studies describe the symptoms occurring in infants that subsequently have EOGBS confirmed on blood culture [27,62].

Clinical Practice

Atypical vital sign observations such as:

- Tachypnoea (Respiratory rate > 60 breaths per minute)
- Temperature instability (< 36ºC, > 38ºC)
- Oxygen saturations lower than expected for age of life
- Tachycardia (Heart rate > 160 beats per minute)

Other symptoms include:

- Poor feeding/Feed intolerance
- Lethargy or irritability
- Apnoea
- Seizures
- Abnormal neurological examination (altered tone)
- Requirement for ICU care (cardiopulmonary resuscitation, mechanical ventilation, signs of shock)
- Signs of respiratory distress
- Jaundice within 24 hours of life
- Neonatal encephalopathy
- Altered glucose homeostasis.

Clinical Question 2.15: **What investigations should be performed on an infant as part of a sepsis evaluation?**

Evidence Statement

Good quality evidence for the use of blood cultures from a Cochrane systematic review found that microbial cultures of blood or other sterile body fluids are the gold standard for diagnosis of bacterial sepsis in infants [63,64]. However, blood cultures in infants have low sensitivity due to a low degree of bacteraemia, small inoculation volume into blood culture bottles and use of maternal intrapartum antibiotics [63,64]. Results of culture investigations are usually not available for 24 to 72 hours and despite automated continuous blood culture monitoring systems further testing is usually required such as subculture for specific assays for pathogen identification [63,64].

Low quality data from several retrospective and observational studies show that low WCC, low neutrophil counts and high I:T neutrophil ratios were associated with increasing odds of infection, with high specificity and negative predictive value but low sensitivity for all indices. No value could reliably exclude sepsis [65-69].

There are no haematological biomarkers that are sufficiently sensitive to act as a sole indicator to initiate empiric antibiotic therapy. The diagnostic value of some biomarkers such as CRP increase when serial measurements are made and the diagnosis of sepsis is unclear due to negative blood cultures. Additionally other biomarkers may be useful when used in combination, such as procalcitonin or CD64[70].

There is moderate quality evidence from a multi-centre randomised controlled trial (NeoPIns) for the use of procalcitonin to guide decision making for suspected early onset sepsis. [71] There is good quality evidence for performing lumbar puncture in cases of bacteraemia from a systematic review and meta-analysis which found 23% of all GBS invasive cases (95% CI, 14%-32%) were meningitis. Among EOGBS cases, 78% (95% CI, 67%-88%) had sepsis and 16% (95% CI, 8%-25%) had meningitis. The meningitis/sepsis ratio was 0.18 (95% CI, .13-.25)[72].

Clinical Practice

As part of the initial sepsis evaluation, a blood culture should be obtained under aseptic technique, using a solution of alcoholic chlorhexidine and allowing it to dry for one minute, as bactericidal activity is not immediate.

Blood volumes, ideally of 0.5-1ml are recommended and the sample should make up between 10-20% of the paediatric blood culture bottle medium volume.

Blood culture remains the gold standard for the diagnosis of early onset GBS disease in infants.

A full blood count should be performed as part of the initial work up.

Additionally, in an infant who is symptomatic at presentation, or who develops symptoms of sepsis consider a lumbar puncture to exclude meningitis, if clinically indicated. This should only be performed after the infant's clinical condition has stabilised, making it safe to do so.

Any infant who has a positive blood culture result should undergo a lumbar puncture to exclude meningitis. This should only be performed after the infant's clinical condition has stabilised, making it safe to do so.

Recommendations

16. **We suggest that investigations for a sepsis evaluation in an infant should include:**
    - **Blood culture obtained in a sterile fashion.**
    - **Full Blood Count.**
    - **Lumbar puncture should be considered.**

Clinical Question 2.16: **What antibiotic regime is recommended for the infant?**

Evidence Statement

A 2021 systematic review evaluated five randomised controlled trials comparing various antibiotic regimes used in the treatment of early onset neonatal sepsis (ampicillin and gentamicin versus penicillin and gentamicin; piperacillin-tazobactam versus amikacin; ticarcillin-clavulanic acid versus piperacillin and gentamicin; piperacillin versus ampicillin and amikacin; ceftazidime versus benzylpenicillin and gentamicin). All trials were at high risk of bias. No study showed any difference in all-cause mortality, serious adverse events, respiratory support, circulatory support, nephrotoxicity, neurological developmental impairment, necrotising enterocolitis or ototoxicity. The evidence was of very-low quality and the authors concluded that current evidence could not confirm or reject one antibiotic regimen being superior to another [73].

The AAP Guideline on Treatment of EOGBS Disease recommends that "*ampicillin, together with an aminoglycoside, is the primary recommended therapy for infants up to seven days of age*." Alternative dosing regimens are provided for Penicillin G for infants greater than 34 weeks gestational age and less than seven days old (bacteraemia Penicillin G 50,000units/kg every 12 hours; meningitis 150,000units/kg every eight hours) [27,74]. Note: Penicillin G 50,000 units/kg equates to benzylpenicillin 30mg/kg. Gentamicin dosing is not specified.

The dosing regimen described in the NICE NG195 Clinical Guideline for Suspected Infection is benzylpenicillin 25mg/kg 12 hourly – the dosing interval to be shortened to eight hourly based on clinical judgement. Gentamicin dosing is described as 5mg/kg every 36 hours [75]. The RCOG Green-top guideline recommends that "*babies with clinical signs of EOGBS … treated with penicillin and gentamicin within an hour*", no other specific recommendations in terms of dosing or frequency are made. [17]

Recent national level epidemiological data from Australia have shown variation in prescribing practices across different states and clinical settings; national therapeutic guidelines recommend benzylpenicillin 50mg/kg 12 hourly and gentamicin 5mg/kg 24 hourly for the treatment or prophylaxis of EOS. [76,77]

Clinical Practice

In Irish neonatal units, a regime of IV benzylpenicillin and IV gentamicin is usual.

Refer to local antimicrobial guidelines for information on dosing.

Recommendations

17. **We suggest that a regime of IV benzylpenicillin and IV gentamicin is usual for EOGBS prophylaxis in infants, refer to local guidelines in maternity unit for information on dosing.**

Clinical Question 2.17: **What are the absolute indications for treatment of the infant with IV antibiotics?**

Evidence Statement

Low quality evidence from epidemiological studies show that 1-2% of culture proven GBS EOS have a sibling previously affected with GBS disease. [59] Clinical signs and symptoms are well described in the literature and though all are indicators of an unwell infant, no sign or signs is/are specific for early onset disease. Additionally, there is no prognostic value associated with any specific symptom or combination of symptoms. [27,61]. Moderate quality evidence from a prospective, cohort study describes the development of symptoms at an earlier stage (within the first 6 hours of life) in those infants who have been exposed to IAP that subsequently have culture-confirmed EOGBS [62]. The evidence for treatment where there is culture confirmed sepsis in a twin or triplet comes largely from data in preterm infants. [78].

Clinical Practice

- All infants who are symptomatic, should receive antibiotics after a sepsis evaluation is performed, irrespective of the presence of risk factors.
- Where there is a positive blood culture in a twin, triplet or other infant from a multiple pregnancy, an infant should receive IV antibiotics.
- Where there is a history of a previous sibling affected by early onset invasive GBS disease, the infant should be reviewed and the decision to administer IV antibiotics should be made by a senior clinician.
- Where a maternal blood culture taken in the perinatal period is positive, the infant should be reviewed by a senior clinician; consider giving IV antibiotics.

Recommendations

18. **We suggest commencing treatment with IV antibiotics (EOGBS prophylaxis) for any infant who is symptomatic. We also suggest commencing treatment with IV antibiotics for an infant where a sibling in a multiple birth has a positive blood culture. We suggest considering treatment where there is a history of invasive EOGBS in a previous sibling.**

Clinical Question 2.18: **What care should be offered to asymptomatic infants where risk factors for EOGBS are present?**

Evidence Statement

Moderate quality evidence exists from systematic reviews and meta-analyses for the use of the EOS sepsis calculator showing reduction in antibiotic usage and non-inferiority in missed cases of EOS when compared with conventional management techniques. [79,80]

Moderate quality evidence from meta-analysis of individual patient data shows that up to 44.0% [95% CI, 37.6%-50.6%] of culture confirmed sepsis would be assigned to routine care at birth, dropping to 27.7% [95% CI, 22.1%-34.0%] at 12 hours of age when using the sepsis calculator. [81]

Lower quality, single centre, observational and quality improvement projects have confirmed similar findings in terms of antibiotic usage and laboratory investigations. [82-84]

A systematic review and meta-analysis of the sensitivity of the sepsis calculator compared with NICE Guideline management was performed in 2019. Data were taken from 11 studies. Both retrospective and prospective studies were included. The meta-analysis found that when compared with NICE guidelines, the probability of the sepsis calculator missing a case of early onset sepsis (in addition to those missed by NICE) was between 0.19 [0.11-0.29] and 0.31 [0.17-0.49] and the probability of missing cases was greater in a subset of babies exposed to chorioamnionitis (0.33 [0.11-0.67] to 0.56 [0.25-0.82]). The authors state there was no significant heterogeneity (I^2 0-37%) across the studies. It is worth noting that the studies came from healthcare settings with and without universal GBS screening. The authors also note that at the time of their review, data was available for only 75 cases of EOS, and that in order to validate the calculator model it is likely that between 100 and 200 external cases would be required [85].

Clinical Practice

Current practice has moved away from the treatment of infants based on risk factors alone to reduce the number of infants exposed unnecessarily to IV antibiotics. See algorithm 4 Suggested care pathways for asymptomatic infants with risk factors.

An asymptomatic infant with risk factors (as per Clinical Question 12) should be evaluated by one of the following management strategies:

a. clinical, risk-based approach such as:
    i. NG 195 Neonatal infection: antibiotics for prevention and treatment https://www.nice.org.uk/guidance/ng195
    ii. Local clinical, risk-based approach or
b. a multivariate prediction tool (the Kaiser Permanente Early Onset Sepsis Calculator https://neonatalsepsiscalculator.kaiserpermanente.org/)

The recommendation to use either of these management approaches is based on the evidence that is currently available.

Within the setting of Irish neonatal units, there is a wide variety of practice when it comes to managing asymptomatic infants [23]. Local guidelines may be in use which deviate from those set out by NICE or the sepsis calculator. To inform best practice in the future, we recommend that local guidelines be subject to prospective audit and ongoing review of clinical practice and outcomes in relation to published incidence figures of early onset invasive GBS disease.

Recommendations

19. **We suggest that each maternity unit should choose and implement one of the following GBS neonatal risk factor management options:**
    1. **A clinical, risk-based approach, e.g.:**

       NICE Guideline NG 195

       Locally defined risk-based approach
    2. **Kaiser Permanente Early Onset Sepsis Calculator.**

Clinical Question 2.19: **Which infants with risk factors should be offered vital sign observation on the postnatal ward?**

Evidence Statement

Moderate quality evidence exists from systematic reviews and meta-analyses for the use of the EOS sepsis calculator showing non-inferiority in missed cases of EOS when compared with conventional management techniques. [79,80]

A systematic review and meta-analysis of the sensitivity of the sepsis calculator compared with NICE Guideline management was performed in 2019. Data were taken from 11 studies. Both retrospective and prospective studies were included. The meta-analysis found that when compared with NICE guidelines, the probability of the sepsis calculator missing a case of early onset sepsis (in addition to those missed by NICE) was between 0.19 [0.11-0.29] and 0.31 [0.17-0.49] and the probability of missing cases was greater in a subset of babies exposed to chorioamnionitis (0.33 [0.11-0.67] to 0.56 [0.25-0.82]). The authors state there was no significant heterogeneity (I^2 0-37%) across the studies. It is worth noting that the studies came from healthcare settings with and without universal GBS screening. [85]

Clinical Practice

Following evaluation with either of the management strategies discussed in Clinical Question 2.18; infants should be categorised into two groups:

1. Require treatment with a septic work up and IV antibiotics or,
2. Suitable for admission to the postnatal ward and regular monitoring of vital signs.

Recommendations

20. We recommend that care for infants following assessment as per CQ2.18 should comprise either: regular monitoring of vital signs on the postnatal ward or a sepsis evaluation and IV antibiotics.

Clinical Question 2.20: **What ongoing care is recommended for infants admitted to the postnatal ward for vital sign observation?**

Evidence Statement

Conflicting evidence exists both on the frequency and duration of vital sign observation, depending on which management strategy is used.

The Newborn Early Warning System, in use in the UK, was developed following a single-centre study which had both retrospective and prospective aspects. [86] The system was developed to identify all "At-Risk Newborn Infants" and is not specific for early onset sepsis, therefore should be considered low quality evidence in the context of EOS. The Newborn Early Warning System informs the NICE NG195 Guideline; that vital signs should be performed at 1 and 2 hours post review, and two hourly thereafter until 12 hours of age for infants under observation on the postnatal ward.

There is moderate quality evidence for the use of four hourly monitoring for 24 hours as advised by the sepsis calculator when used as part of this management strategy. The strategy for vital sign monitoring is not validated independently of the calculator. [87]

Low quality evidence from observational and epidemiological studies (see below) suggests that most infants will become symptomatic within the first 24 hours of life and abnormalities will be detected on newborn examination.

In a large population based retrospective study with data for 104,000 term and preterm infants 70% of term infants developed symptoms of EOS (all pathogens) within the first 6 hours of life. Overall, 94% infants with EOS had onset of symptoms within the first 24 h of life. The median (IQR) time to start of EOS-symptoms was 3.0 h (1.0, 13.0). [88] Another epidemiological study reports 57-70% of infants were symptomatic within the first 12 hours. [59] Prospective studies show that up to half of infants who develop culture positive EOS are asymptomatic at birth. [87]

There is low-moderate evidence from observational studies [89,90] that delaying antimicrobial treatment in cases of sepsis in the paediatric population increases morbidity and mortality. Evidence specific relating to timing of antimicrobial administration for treatment of sepsis in term infants is lacking.

Clinical Practice

Following admission to the postnatal ward, infants should have regular vital sign observations (temperature, heart rate, respiratory rate and oxygen saturations)**.** The duration of vital sign observation should be agreed locally. (Recommend 4 to 6 hourly for at least 24 hours).

The overall condition of the infant, including feeding, colour, level of alertness and tone should also be monitored.

Abnormal vital signs or concerns about the condition of the infant should be reported to medical staff and a full clinical assessment made.

Any infant who develops symptoms or signs on the postnatal ward during the observation period should be considered for septic work up and administration of IV antibiotics.

If there are no clinical concerns following completion of the observation period on the postnatal ward, the infant may be discharged. Prior to discharge, a discussion should be had with parents about how to recognise signs and symptoms in their baby that warrant immediate assessment and advice on how to access the appropriate care.

Recommendations

21. **We suggest observing vital signs of the infant on the postnatal ward. Frequency and duration of observations should be agreed locally, while we suggest 4 to 6 hourly for a minimum of 24 hours. The overall condition of the infant should be monitored.**

Clinical Question 2.21: **If a woman has GBS diagnosed on HVS/ C&S within the first postpartum week , what care should be offered to the infant?**

Evidence Statement

This recommendation is based on current practice. In the context of an asymptomatic infant, no relevant studies have been identified. In the future, prospective studies would be beneficial to update practice in this area.

Clinical Practice

The mother should be notified of her positive result.

Parents should be advised on the recognition of signs and symptoms of illness in their infant that warrant immediate medical review as a routine part of the newborn examination. Providing written information regarding the recognition of signs and symptoms of illness in the newborn may be beneficial; these symptoms are common to many illnesses in the infant, including, but not limited to EOGBS, late-onset GBS and others. No further input is warranted if the infant remains well.

Recommendations

22. **If a woman has GBS diagnosed on a vaginal swab within the first week of life, we suggest that the mother be notified of her result, and no further input is warranted if the infant remains well. If GBS UTI is identified on MSU we recommend maternal antibiotic treatment as described above. If the woman has been discharged the positive result can also be shared with her GP.**

Section 6: National Surveillance of GBS Invasive Disease

Clinical Question 2.22: **How should national epidemiological surveillance of invasive GBS disease be performed?**

Evidence Statement

'Disease surveillance is an information-based activity involving the collection, analysis and interpretation of large volumes of data. The information is then used in a number of ways to evaluate the effectiveness of control and preventative health measures, monitor changes in infectious agents e.g. antimicrobial resistance, support health planning and the allocation of appropriate resources, identification of high risk populations or areas to target interventions and provide a valuable archive of disease activity for future reference' https://hpsc.ie/abouthspc/whatisdiseasesurveillance).

A GBS vaccine is a WHO priority with the recent ratification of the defeating meningitis by 2030 roadmap [91]. Maternal antibodies against type-specific capsular polysaccharide are protective. The relative prevalence of circulating specific capsular serotypes has been critical to determining the optimal serotype valence in vaccines under development: In the mid-1970's serotype Ia, Ib, II and III were most prevalent in invasive neonatal disease. By the 1990's, serotype V emerged. More recently, there has been the emergence of serotype IV due in part to the introduction of the IV capsular locus in GBS strains more associated with serotype Ia and III and virulent for mothers and infants. Changes in serotype prevalence has resulted in changes to the valency for conjugate vaccines under development from trivalent (Ia, Ib and III) to pentavalent (Ia, Ib, II, III, V) and to a recent hexavalent additionally including serotype IV [92,93].

A limitation of molecular diagnostic methods is the failure to detect organisms due to loss of the target nucleic acid sequences either through deletion or mutation. Continuous surveillance of circulating microbial populations for the emergence of mutant strains is critical to monitor the accuracy of molecular detection tests. Surveillance of the GBS Xpert test (US-IVD), 2012-2018 identified a number of PCR-negative and culture-positive isolates. Whole genome sequencing of GBS isolates from the United States and Ireland identified chromosomal deletions in the region of the (cfb) gene used as target for the Xpert GBS real time PCR tests. Prospective surveillance studies showed a frequency GBS isolates containing deletions of <1% in three geographical locals and 7% in a fourth location [94].

Clinical Practice

- GBS disease is a mandatory notifiable disease under the Infectious Disease Regulations[95]
- Bacterial isolates from invasive GBS cases (both mothers and babies) should be sent to the Irish Meningitis and Sepsis Reference Laboratory (IMSRL) in Children's Health Ireland at Temple Street
- Invasive GBS disease should be reported through the EARS-net surveillance system in line with existing laboratory practices
- Annual statistics on invasive GBS disease should be analysed at both a hospital and national level
- If a women had a negative GBS PCR intrapartum vaginal swab, but either she or her infant developed invasive GBS disease, then the isolate should be referred to the IMSRL for further analysis and the discordant result flagged with the reference laboratory.

Recommendations

23. **Each unit should report and audit their own incidence rate of EOGBS.**
24. **We recommend that laboratories should send GBS isolates from sterile sites to the IMSRL for further analysis and sequencing to help examine national trends. Laboratories should communicate with the IMSRL if the organism was not detected using molecular methods.**

Chapter 3: Development of Clinical Practice Guideline

3.1 Literature search strategy

Regarding the obstetric section of the Guideline, a comprehensive literature review was performed, searching the MEDLINE database & Cochrane library for clinical practice guidelines regarding the prevention of EOGBS disease, restricted to those in the English language, in the past ten years. This entailed a keyword and MeSH search using the terms "group B streptococcal disease" "group B streptococcus" "streptococcus agalactiae".

Our search revealed six guidelines: RCOG, CDC, SOGC, RANZCOG, New Zealand consensus guidelines, and the European Consensus Conference. These guidelines are listed in the bibliography. References included in these guidelines were also reviewed as well as additional references identified through the literature review.

A comprehensive paediatric literature review was performed, searching MEDLINE, Cochrane Library and EMBASE databases for systematic review and meta-analyses, international publications and epidemiological studies related to EOGBS disease. Only publications in the English language were reviewed. All publication dates were considered. Additional publications were identified from the bibliography of reviewed articles. Clinical practice guidelines including the AAP and NICE guidelines on the management of infants with risk factors for EOS were reviewed and are listed in the bibliography.

3.2 Appraisal of evidence

Following a comprehensive literature review the quality, validity and relevance of the evidence gathered were critically appraised by the Guideline developers under the following headings:

- Study design
- Relevance of primary and secondary outcomes
- Consistency of results across studies
- Magnitude of benefit versus magnitude of harm
- Applicability to practice context

A number of evidence-based recommendations for prevention of EOGBS disease were agreed upon. They have been adapted to reflect care in the Irish healthcare setting.

3.3 AGREE II process

While being developed, the Guideline was assessed using the AGREE II checklist (Appendix 4) as recommended by the Department of Health in the 'How to Develop a National Clinical Guideline: a manual for guideline developers', 2019.[11]

11 Department of Health. How to develop a National Clinical Guideline: A manual for guideline developers. Available at: https://www.gov.ie/en/collection/cd41ac-clinical-effectiveness-resources-and-learning/

The purpose of AGREE II is to provide a framework to:

1. Assess the quality of guidelines
2. Provide a methodological strategy for the development of guidelines
3. Inform what information and how information ought to be reported in guidelines

3.4 Literature review

Details of supportive evidence-based literature for this Guideline are reported in chapter two.

The following steps were undertaken to ensure a comprehensive literature review of the available evidence on the prevention of EOGBS. Obstetric literature review was carried out by Dr Alex Dakin, and evidence was reviewed by Dr Maeve Eogan and Dr Sandhya Babu. Paediatric literature review was carried out by Dr Leah Loughlin, and evidence was reviewed by Prof Eugene Dempsey, Dr Wendy Ferguson, Dr Richard Drew. Microbiology recommendations were developed by Dr Richard Drew, Dr Susan Knowles, Dr Lorraine Power, and Dr Mary Meehan. The Guideline group met regularly to review changes and recommendations. The final draft of the Guideline was reviewed by all committee members.

3.5 Grades of recommendation

GRADE offers a transparent and structured process for developing and presenting evidence summaries and for carrying out the steps involved in developing recommendations[12]. While we acknowledge that for this particular work an extensive GRADE approach is not possible, we have used the suggested language set out in the GRADE table when making recommendations [13]. (Appendix 5)

3.6 Future research

An important outcome of the Guideline development process is in highlighting gaps in the evidence base.

The questions of relevance to this Guideline include:

- Each unit should know their own incidence of EOGBS
- Every maternity & neonatal unit should develop a strategy for EOGBS prevention based on the information and care pathways described in this Guideline.
- Ongoing clinical audit should be performed within sites to ensure compliance, safety & efficacy
- Inter-method studies of the prescribed options for screening should be considered
- The Guideline development group will be alert to evolving evidence, particularly in relation to different screening strategies, and will adjust the Guideline as appropriate

12 Guyatt, Gordon, *et al.* "GRADE Guidelines: 1. Introduction – GRADE Evidence Profiles and Summary of Findings Tables." *Journal of Clinical Epidemiology*, vol. 64, no. 4, 2011, pp. 383-94, https://doi.org/10.1016/j.jclinepi.2010.04.026

13 SMFM adopts GRADE (Grading of Recommendations Assessment, Development, and Evaluation) for clinical guidelines. Society for Maternal-Fetal Medicine (SMFM), Chauhan SP, Blackwell SC. Am J Obstet Gynecol. 2013 Sep;209(3):163-5. doi: 10.1016/j.ajog.2013.07.012. PMID: 23978245 https://pubmed.ncbi.nlm.nih.gov/23978245/

Chapter 4: Governance and Approval

4.1 Formal governance arrangements

This Guideline was written by the Guideline Developers under the direction of the Guideline Programme Team. An Expert Advisory Group was formed to review the Guideline prior to submission for final approval with the National Women and Infants Health Programme. The roles and responsibilities of the members of each group and their process were clearly outlined and agreed.

4.2 Guideline development standards

This Guideline was developed by the Guideline Developer Group (GDG) within the overall template of the HSE National Framework [14] for developing Policies, Procedures, Protocols and Guidelines (2016) (Appendix 6) and under supervision of the Guideline Programme Team (GPT).

A review was conducted by a group of experts, specialists, and advocates (the EAG) prior to approval by the Clinical Advisory Group (CAG) of the National Women and Infants Health Programme (NWIHP) with final sign off for publication by CAG Co-Chairs, the Clinical Director of NWIHP and the Chair of the IOG. See appendix 7 for list of CAG members.

14 Health Service Executive (2016). National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs). Available from: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/

Chapter 5: Communication and Dissemination

A communication and dissemination plan for this Guideline has been developed by the GPT and endorsed by NWIHP.

Effective ongoing clear communication is essential in explaining why the Guideline is necessary and securing continued buy-in. It provides an opportunity to instil motivation within staff, helps overcome resistance to change and gives an opportunity for feedback[15].

The Clinical Guideline will be circulated and disseminated through the Guideline Programme Team as well as through the professional networks who participated in developing and reviewing the document.

Senior management within the maternity units are responsible for the appropriate dissemination of new and updated guidelines. Local hospital groups including Guideline committees are also instrumental in the circulation of new and updated guidelines and promoting their use in the relevant clinical settings.

The HSE will make this Guideline available to all employees through standard networks as well as storing it in the online PPPG repository. Electronic versions available on the NWIHP (https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/clinical-guidelines/) and RCPI websites https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/national-clinical-guidelines-in-obstetrics-and-gynaecology/ and other communication means can be used to maximise distribution. The NWIHP website will also provide a training webinar introducing each Guideline and where relevant a downloadable version of the recommended algorithm will be available.

15 Department of Health (2018). NCEC Implementation Guide and Toolkit. Available at: https://health.gov.ie/national-patient-safety-office/ncec/

Chapter 6: **Implementation**

6.1 Implementation plan

Implementation was considered at the beginning, and throughout the Guideline development process. The local multidisciplinary clinical team, senior executive and clinical management in each maternity and gynaecology unit are ultimately responsible for the appropriate structured adoption and implementation of the guidelines within their area of responsibility. They must ensure that all relevant personnel under their supervision have read and understood the Guideline and monitor both its effectiveness and adoption.

Within each site, local multidisciplinary teams are responsible for the clinical implementation of Guideline recommendations and ensuring that their local clinical practices and processes reflect and are aligned with the Guideline recommendations.

The following have been put in place to help facilitate the implementation of this Guideline.

- Quick Summary Document (QSD) for clinical staff (includes key recommendations, auditable standards, algorithms and recommended reading)
- Clinical Guideline mobile application
- Plain language summary

6.2 Education plans required to implement the Guideline

It is acknowledged that this Guideline should be complemented by ongoing education, training and assessment where required. Multidisciplinary education on implementation of this Guideline should be provided both locally and nationally.

6.3 Barriers and facilitators

To ensure successful implementation of guidelines, it is first necessary to look at potential barriers and facilitators. Taking these into account when developing the implementation plan should improve levels of support from relevant users. (DOH 2018, 2019)

Barriers may be categorised as internal (specific to the Guideline itself) or external (specific to the clinical environment).

The Guideline Development Group has aimed to address any internal barriers during the development of this Guideline.

Potential external barriers include:

- Structural factors (e.g. budget or service redesign)
- Organisational factors (e.g. lack of facilities or equipment)
- Individual factors (e.g. knowledge, skills, training)
- Patient perceptions.

In the case of this Guideline, it will be necessary to examine possible barriers and consider implementation strategies to address them. For example, this may include discussion with relevant management groups with regards to budgetary impact or providing training to the relevant staff. Additional staff and infrastructural laboratory resources will be required to introduce culture based or molecular screening to units who have not previously offered this. The economic impact of these various screening modalities is being assessed in the context of an ongoing UK based clinical trial[22].

Antenatal and postpartum parent education could be augmented to offer information on GBS disease including provision of written information regarding the recognition of signs and symptoms of illness in the newborn, there are economic, organisational and implementation barriers to this.

6.4 Resources necessary to implement recommendations

The implementation of this Guideline should be undertaken as part of the quality improvement of each hospital. Hospitals should review existing service provision against this Guideline, identifying necessary resources required to implement the recommendations in this Guideline.

In the case of this Guideline, each maternity unit should first decide the screening strategy they wish to employ and identify any material human or resource gaps, including (staff, service user and allied community) educational and training requirements to successfully implement same.

Chapter 7: Audit and Evaluation

7.1 Introduction to audit

It is important that both implementation of the Guideline and its influence on outcomes are audited to ensure that this Guideline positively impacts on patient care. Institutions and health professionals are encouraged to develop and undertake regular audits of Guideline implementation. Personnel tasked with the job of conducting the audit should be identified on receipt of the most recent version of the Guideline.

7.2 Auditable standards

Audit using the key recommendations as indicators should be undertaken to identify where improvements are required and to enable changes as necessary. Audit should also be undertaken to provide evidence of continuous quality improvement initiatives.

Auditable standards for this Guideline include:

1. Each unit should know their own annual incidence rate of EOGBS
2. Ongoing clinical audit should be performed within sites to ensure compliance, safety & efficacy with the chosen maternal and neonatal strategies for prevention of EOGBS – this can include (but is not restricted to) timing of screening, availability of actionable results, timing and appropriateness of antibiotic therapy, timing and appropriateness of neonatal sepsis screening, timing and appropriateness of neonatal vital sign observation on the postnatal ward.
3. Audit of prevalence of clindamycin resistant GBS.

7.3 Evaluation

Evaluation is defined as a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved [16].

Implementation of this Guideline will be audited periodically at national level, with standards for this set by the NWIHP. Evaluation of the auditable standards should also be undertaken locally by senior hospital clinical management to support implementation.

16 HIQA. National Standards for Safer Better Healthcare. Heal Inf Qual Auth [Internet]. 2012 [cited 2022 Oct 19]; Available from: https://www.hiqa.ie/reports-and-publications/standard/national-standards-safer-better-healthcare

Chapter 8: Revision Plan

8.1 Procedure for the update of the Guideline

It may be a requirement to amend, update or revise this Guideline as new evidence emerges. This Guideline will be reviewed at national level every three years, or earlier if circumstances require it, and updated accordingly.[17]

The Guideline Development Group will be asked to review the literature and recent evidence to determine if changes are to be made to the existing Guideline. If the Guideline Development Group are unavailable, the GPT along with the NWIHP senior management team will select a suitable expert to replace them.

If there are no amendments required to the Guideline following the revision date, the detail on the revision tracking box must still be updated which will be a new version number and date.

The recommendations set out in this Guideline remain valid until a review has been completed.

8.2 Method for amending the Guideline

As new evidence become available it is inevitable that Guideline recommendations will fall behind current evidence based clinical practice. It is essential that clinical guidelines are reviewed and updated with new evidence as it becomes available.

In order to request a review of this Guideline one of the following criteria must be met:

a. 3 years since the Guideline was published

b. 3 years since last review was conducted

c. Update required as a result of new evidence

Correspondence requesting a review of the Guideline should be submitted to the National Women and Infants Health Programme. Any such requests should be dealt with in a timely manner.

17 Health Service Executive (2016). National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs). Available from: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/

Chapter 9: **References**

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American Society for Microbiology: Guidelines for the Detection of Group B Streptococcus https://asm.org/Guideline/Guidelines-for-the-Detection-and-Identification-of

NICE guideline NG195: Neonatal infection: antibiotics for prevention and treatment https://www.nice.org.uk/guidance/ng195

Society of Obstetricians and Gynaecologists of Canada: Management of Group B Streptococcal Bacteriuria in Pregnancy https://www.jogc.com/article/S1701-2163(16)35246-X/pdf

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Supporting Evidence

GRADE: http://www.gradeworkinggroup.org/

AGREE: http://www.agreetrust.org/agree-ii/

HSE: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/

Glossary
(for the Purpose of this Guideline)

AGREE Appraisal of Guidelines for Research and Evaluation

ACOG American College of Obstetricians and Gynaecologists

CAG Clinical Advisory Group

EAG Expert Advisory Group

EOGBS Early Onset (neonatal) Group B Streptococcus disease

GBS Group B Streptococcus

GPT Guideline Programme Team

GRADE Grading of Recommendations, Assessments, Developments and Evaluations

HIQA Health Information and Quality Authority

HSE Health Service Executive

IOG Institute of Obstetricians and Gynaecologists

IAP Intrapartum Antibiotic Prophylaxis

FIGO International Federation of Gynaecology and Obstetrics

NICE The National Institute for Health and Care Excellence

NCEC National Clinical Effectiveness Committee

NWIHP National Women and Infants Health Programme

PCR Polymerase Chain Reaction

PPPG Policy, Procedures, Protocols and Guidelines

RCOG Royal College of Obstetricians and Gynaecologists

RCPI Royal College of Physicians of Ireland

SOGC The Society of Obstetricians & Gynaecologists Canada

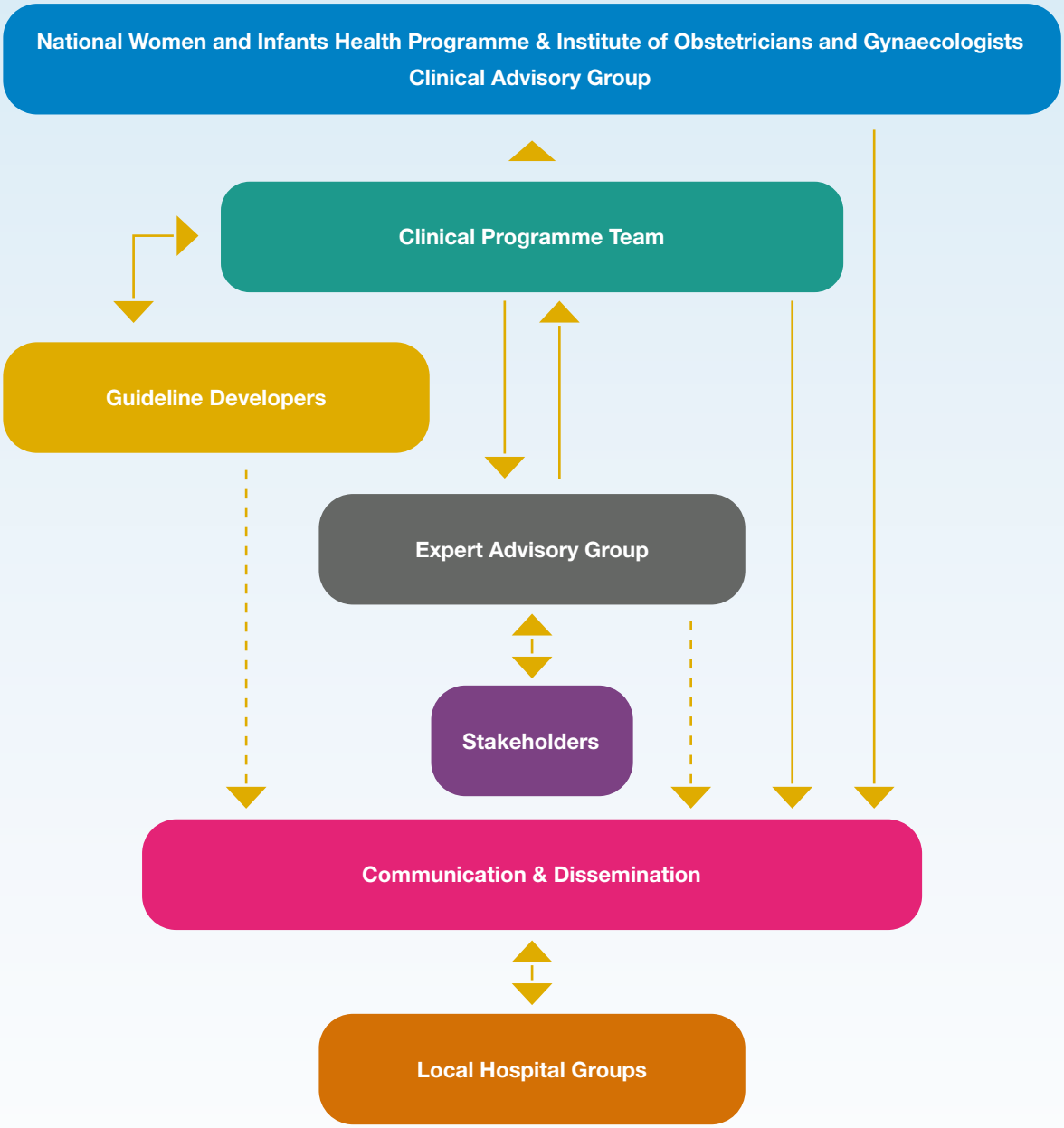
Appendix 1: **Expert Advisory Group Members 2021-**

Name	Profession	Location (2021)
Dr Fergus McCarthy	Consultant Obstetrician, Gynaecologist, Senior Lecturer and Maternal-Fetal Medicine Sub-specialist	Cork University Maternity Hospital, University College Cork
Dr Mairead Butler	Consultant Obstetrician and Gynaecologist	University Hospital Waterford
Prof Declan Keane	Professor of Obstetrics and Gynaecology	National Maternity Hospital Dublin, Royal College of Surgeons in Ireland
Dr Katherine Astbury	Consultant Obstetrician and Gynaecologist Gynaecology Oncology Sub-specialist	University Hospital Galway
Dr Sarah Petch	Specialist Registrar, Obstetrics and Gynaecology	National Maternity Hospital Dublin
Dr Orla Donohoe	Specialist Registrar, Obstetrics and Gynaecology	Sligo University Hospital
Prof John Murphy	Consultant Neonatologist and Clinical Lead for the National Clinical Programme for Paediatrics and Neonatology	National Women and Infants Health Programme
Ms Siobhan Canny	Group Director of Midwifery	Saolta University Health Care Group
Ms Fiona Hanrahan	Director of Midwifery and Nursing	Rotunda Hospital Dublin
Ms Margaret Quigley	National Lead for Midwifery	Office of Nursing and Midwifery Services Director
Prof Valerie Smith	Professor of Midwifery	School of Nursing and Midwifery, Trinity College Dublin
Ms Triona Cowman	Director of the Centre for Midwifery Education	Centre for Midwifery Education, Coombe Women & Infants University Hospital
Ms Janet Murphy	Advanced Midwifery Practitioner	University Hospital Waterford

Attendee	Profession	Location (2021)
Dr Ciara McCarthy	General Practitioner and ICGP Women's Health Lead	Irish College of General Practitioners
Mr Fergal O' Shaughnessy *And* Dr Brian Cleary *(Shared nomination)*	Senior Pharmacist, Honorary Lecturer *And* Chief Pharmacist, Honorary Clinical Associate Professor and Medications Lead, Maternal & Newborn Clinical Management System	Rotunda Hospital Dublin Royal College of Surgeons in Ireland
Ms Marie Finn	Medical Social Work Counsellor	Saolta University Health Care Group
Ms Marie Culliton	Lab Manager/Chief Medical Scientist	National Maternity Hospital Dublin
Ms Marita Hennessy	Post-Doctoral Researcher	Pregnancy Loss Research Group, INFANT Centre, University College Cork
Ms Niamh Connolly-Coyne *And* Ms Mandy Daly *(Shared nomination)*	Board of Directors	Irish Neonatal Health Alliance
Ms Caroline Joyce	Principal Clinical Biochemist PhD Candidate	Cork University Hospital University College Cork
Dr Richard Duffy	Consultant Perinatal Psychiatrist	Rotunda Hospital Dublin
Ms Clare Farrell	Physiotherapy Manager	Coombe Women & Infants University Hospital
Ms Fiona Dunlevy *And* Ms Sinéad Curran *(Shared nomination)*	Dietician Manager	Coombe Women & Infants University Hospital National Maternity Hospital
Dr Nicholas Barrett	Lead for Obstetric Anaesthesiology services	Limerick University Hospital
Dr Brendan Fitzgerald	Consultant Perinatal Pathologist	Cork University Hospital
Dr Niamh Conlon	Consultant Histopathologist	Cork University Hospital
Ms Georgina Cruise	Service Manager	Patient Advocacy Ireland

Appendix 2:
Guideline Programme Process

Guideline Programme Process



Appendix 3: Description of the Strengths and Limitations of the Different GBS Screening Strategies

Option	Pathway	Description	Strengths	Limitations	Notes
1	Risk based screening	A clinical risk factor-based system targeting those with specific clinical indicators (including prolonged rupture of membranes, bacteriuria, an earlier child with EOGBS, and maternal fever) for GBS infection.	Recommended by RCOG	Clinical risk factors are poorly associated with vertical GBS transmission. Up to 40% of the cases of EOGBS invasive infection do not have maternal risk factors associated and could therefore not be prevented under risk-based policies.	A recent meta-analysis did not show a significant benefit of risk-based versus no screening protocol, and that universal screening was associated with a reduced risk of EOGBS compared with risk-factor based [32]

Option	Pathway	Description	Strengths	Limitations	Notes
2	Molecular screening at induction/ prelabour term SROM	PCR based screening at particular time point – e.g. IOL, prelabour SROM, or all patients at onset of labour	Real-time assessment of GBS carriage, highly sensitive and specific real-time alternative for triaging mothers for IAP and babies for appropriate surveillance	Additional resource requirement but the added expenditure could be further justified by reducing unnecessary treatment, reduced drug resistance and avoidance of unnecessary neonatal surveillance and interventions and needless separation of babies from mothers at crucial bonding periods.	Potentially challenging to operationalise for 'all women at onset of labour'. Some units using for people at higher risk of prolonged ROM who are likely to have sufficient time for PCR testing before delivery (e.g. IOL, prelabour SROM), in conjunction with option 1 for spontaneous labour
3	Routine antenatal screening (35-37 weeks)	Bacteriological screening (vaginal and rectal swab)	Provides a result for all patients who attend for screening	Concerns regarding antibiotic stewardship and risk of anaphylaxis, concerns regarding false negative or false positive screening results or people labouring prior to screening, and concerns regarding the potential for screening to impact on capacity and resources in hospitals	RCOG guidance directs that maternal request is not an indication for screening – this guideline development group recommends is that the woman's preferences should be discussed in context of a request for antenatal screening.

Appendix 4: AGREE II Checklist[18]

AGREE Reporting Checklist 2016

This checklist is intended to guide the reporting of Clinical Practice Guidelines.

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
DOMAIN 1: SCOPE AND PURPOSE		
1. OBJECTIVES *Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.*	☐ Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.) ☐ Expected benefit(s) or outcome(s) ☐ Target(s) (e.g., patient population, society)	
2. QUESTIONS *Report the health question(s) covered by the guideline, particularly for the key recommendations.*	☐ Target population ☐ Intervention(s) or exposure(s) ☐ Comparisons (if appropriate) ☐ Outcome(s) ☐ Health care setting or context	
3. POPULATION *Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply.*	☐ Target population, sex and age ☐ Clinical condition (if relevant) ☐ Severity/stage of disease (if relevant) ☐ Comorbidities (if relevant) ☐ Excluded populations (if relevant)	
DOMAIN 2: STAKEHOLDER INVOLVEMENT		
4. GROUP MEMBERSHIP *Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/ rating the evidence and individuals involved in formulating the final recommendations.*	☐ Name of participant ☐ Discipline/content expertise (e.g., neurosurgeon, methodologist) ☐ Institution (e.g., St. Peter's hospital) ☐ Geographical location (e.g., Seattle, WA) ☐ A description of the member's role in the guideline development group	

18 AGREE Reporting Checklist is available on the AGREE Enterprise website, a free and open access resource to support the practice guideline field (www. agreetrust.org)

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
5. TARGET POPULATION PREFERENCES AND VIEWS *Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.*	☐ Statement of type of strategy used to capture patients'/publics' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences) ☐ Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups) ☐ Outcomes/information gathered on patient/public information ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
6. TARGET USERS *Report the target (or intended) users of the guideline.*	☐ The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators) ☐ How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)	
DOMAIN 3: RIGOUR OF DEVELOPMENT		
7. SEARCH METHODS *Report details of the strategy used to search for evidence.*	☐ Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL) ☐ Time periods searched (e.g., January 1, 2004 to March 31, 2008) ☐ Search terms used (e.g., text words, indexing terms, subheadings) ☐ Full search strategy included (e.g., possibly located in appendix)	
8. EVIDENCE SELECTION CRITERIA *Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.*	☐ Target population (patient, public, etc.) characteristics ☐ Study design ☐ Comparisons (if relevant) ☐ Outcomes ☐ Language (if relevant) ☐ Context (if relevant)	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
9. STRENGTHS & LIMITATIONS OF THE EVIDENCE *Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.*	☐ Study design(s) included in body of evidence ☐ Study methodology limitations (sampling, blinding, allocation concealment, analytical methods) ☐ Appropriateness/relevance of primary and secondary outcomes considered ☐ Consistency of results across studies ☐ Direction of results across studies ☐ Magnitude of benefit versus magnitude of harm ☐ Applicability to practice context	
10. FORMULATION OF RECOMMENDATIONS *Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.*	☐ Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered) ☐ Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures) ☐ How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)	
11. CONSIDERATION OF BENEFITS AND HARMS *Report the health benefits, side effects, and risks that were considered when formulating the recommendations.*	☐ Supporting data and report of benefits ☐ Supporting data and report of harms/side effects/risks ☐ Reporting of the balance/trade-off between benefits and harms/side effects/risks ☐ Recommendations reflect considerations of both benefits and harms/side effects/ risks	
12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE *Describe the explicit link between the recommendations and the evidence on which they are based.*	☐ How the guideline development group linked and used the evidence to inform recommendations ☐ Link between each recommendation and key evidence (text description and/or reference list) ☐ Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
13. EXTERNAL REVIEW *Report the methodology used to conduct the external review.*	☐ Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence) ☐ Methods taken to undertake the external review (e.g., rating scale, open-ended questions) ☐ Description of the external reviewers (e.g., number, type of reviewers, affiliations) ☐ Outcomes/information gathered from the external review (e.g., summary of key findings) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)	
14. UPDATING PROCEDURE *Describe the procedure for updating the guideline.*	☐ A statement that the guideline will be updated ☐ Explicit time interval or explicit criteria to guide decisions about when an update will occur ☐ Methodology for the updating procedure	
DOMAIN 4: CLARITY OF PRESENTATION		
15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS *Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.*	☐ A statement of the recommended action ☐ Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects) ☐ Relevant population (e.g., patients, public) ☐ Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply) ☐ If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline	
16. MANAGEMENT OPTIONS *Describe the different options for managing the condition or health issue.*	☐ Description of management options ☐ Population or clinical situation most appropriate to each option	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
17. IDENTIFIABLE KEY RECOMMENDATIONS *Present the key recommendations so that they are easy to identify.*	☐ Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms ☐ Specific recommendations grouped together in one section	
DOMAIN 5: APPLICABILITY		
18. FACILITATORS AND BARRIERS TO APPLICATION *Describe the facilitators and barriers to the guideline's application.*	☐ Types of facilitators and barriers that were considered ☐ Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation) ☐ Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography) ☐ How the information influenced the guideline development process and/or formation of the recommendations	
19. IMPLEMENTATION ADVICE/TOOLS *Provide advice and/or tools on how the recommendations can be applied in practice.*	☐ Additional materials to support the implementation of the guideline in practice. For example: • Guideline summary documents • Links to check lists, algorithms • Links to how-to manuals • Solutions linked to barrier analysis (see Item 18) • Tools to capitalize on guideline facilitators (see Item 18) • Outcome of pilot test and lessons learned	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
20. RESOURCE IMPLICATIONS *Describe any potential resource implications of applying the recommendations.*	☐ Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs) ☐ Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.) ☐ Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
21. MONITORING/ AUDITING CRITERIA *Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.*	☐ Criteria to assess guideline implementation or adherence to recommendations ☐ Criteria for assessing impact of implementing the recommendations ☐ Advice on the frequency and interval of measurement ☐ Operational definitions of how the criteria should be measured	
DOMAIN 6: EDITORIAL INDEPENDENCE		
22. FUNDING BODY *Report the funding body's influence on the content of the guideline.*	☐ The name of the funding body or source of funding (or explicit statement of no funding) ☐ A statement that the funding body did not influence the content of the guideline	
23. COMPETING INTERESTS *Provide an explicit statement that all group members have declared whether they have any competing interests.*	☐ Types of competing interests considered ☐ Methods by which potential competing interests were sought ☐ A description of the competing interests ☐ How the competing interests influenced the guideline process and development of recommendations	

From: Brouwers MC, Kerkvliet K, Spithoff K, on behalf of the AGREE Next Steps Consortium. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. BMJ 2016;352:i1152. doi: 10.1136/bmj.i1152.

For more information about the AGREE Reporting Checklist, please visit the AGREE Enterprise website at http://www.agreetrust.org.

Appendix 5: **Grades of Recommendations**[19]

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
1 A. Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Consistent evidence from well-performed randomised, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Strong recommendations can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present	We strongly recommend… We recommend that …should be performed/ administered… We recommend that … is indicated/ beneficial/ effective….

19 SMFM adopts GRADE (Grading of Recommendations Assessment, Development, and Evaluation) for clinical guidelines. Society for Maternal-Fetal Medicine (SMFM), Chauhan SP, Blackwell SC. Am J Obstet Gynecol. 2013 Sep;209(3):163-5. doi: 10.1016/j.ajog.2013.07.012. PMID: 23978245 https://pubmed.ncbi.nlm.nih.gov/23978245/

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
1 B. Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Evidence from randomised, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Strong recommendation and applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present	We recommend… We recommend that … should be performed/ administered… We recommend that … is (usually) indicated/ beneficial/ effective…
1 C. Strong recommendation, low-quality evidence	Benefits appear to outweigh risk and burdens, or vice versa	Evidence from observational studies, unsystematic clinical experience, or from randomised, controlled trials with serious flaws. Any estimate of effect is uncertain	Strong recommendation that applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality	We recommend… We recommend that … should be performed/ administered… We recommend that … Is (maybe) indicated/ beneficial/ effective…
2A. Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	Consistent evidence from well-performed randomised, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Weak recommendation: best action may differ depending on circumstances or patients or societal values	We suggest… We suggest that … may/might be reasonable…

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
2B. Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens, some uncertainty in the estimates of benefits, risks and burdens	Evidence from randomised, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Weak recommendation; alternative approaches likely to be better for some patients under some circumstances	We suggest… We suggest that … may/might be reasonable…
2C. Weak recommendation, low-quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens	Evidence from observational studies, unsystematic clinical experience, or from randomised, controlled trials with serious flaws. Any estimate of effect is uncertain	Very weak recommendation: other alternatives may be equally reasonable.	We suggest… is an option We suggest that … may/might be reasonable.
Best practice	A recommendation that is sufficiently obvious that the desirable effects outweigh undesirable effects, despite the absence of direct evidence, such that the grading of evidence is unnecessary			We recommend… We recommend that … should be performed/ administered… We recommend that … Is usually) indicated/ beneficial/effective

Appendix 6: Policies, Procedures, Protocols and Guidelines checklist

The PPPG Checklists were developed to assist staff to meet standards when developing Clinical PPPGs.

Standards for developing clinical PPPG	
Stage 1 initiation	**Checklist**
The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	☐
Synergies/co-operations are maximised across departments/organisations (Hospitals/ Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.	☐
The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.	☐
The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.	☐
The views and preferences of the target population have been sought and taken into consideration (as required).	☐
The overall objective(s) of the PPPGs are specifically described.	☐
The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).	☐
Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	☐
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	☐
The PPPG is informed by the identified needs and priorities of service users and stakeholders.	☐
There is service user/lay representation on PPPG Development Group (as required).	☐
Information and support is available for staff on the development of evidence-based clinical practice guidance.	☐

Stage 2 development	**Checklist**
The clinical question(s) covered by the PPPG are specifically described.	☐
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/ adopted from international guidance, their methodology is appraised and documented).	☐
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	☐
The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	☐
There is an explicit link between the PPPG and the supporting evidence.	☐
PPPG guidance/recommendations are specific and unambiguous.	☐
The potential resource implications of developing and implementing the PPPG are Identified e.g. equipment, education/training, staff time and research.	☐
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	☐
Budget impact is documented (resources required).	☐
Education and training is provided for staff on the development and implementation of evidence- based clinical practice guidance (as appropriate).	☐
Three additional standards are applicable for a small number of more complex PPPGs:	☐
Cost effectiveness analysis is documented.	☐
A systematic literature review has been undertaken.	☐
Health Technology Assessment (HTA) has been undertaken.	☐
Stage 3 governance and approval	**Checklist**
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	☐
The PPPG has been reviewed by independent experts prior to publication (as required).	☐
Copyright and permissions are sought and documented.	☐
Stage 4 communication and dissemination	**Checklist**
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	☐
Plan and procedure for dissemination of the PPPG is described.	☐
The PPPG is easily accessible by all users e.g. PPPG repository.	☐

Stage 5 implementation	**Checklist**
Written implementation plan is provided with timelines, identification of responsible persons/ units and integration into service planning process.	☐
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	☐
Education and training is provided for staff on the development and implementation of evidence- based PPPG (as required).	☐
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	☐
Stage 6 monitoring, audit, evaluation	**Checklist**
Process for monitoring and continuous improvement is documented.	☐
Audit criteria and audit process/plan are specified.	☐
Process for evaluation of implementation and (clinical) effectiveness is specified.	☐
Stage 7 revision/update	**Checklist**
Documented process for revisions/updating and review, including timeframe is provided.	☐
Documented process for version control is provided.	☐

To view in full refer to website: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/

Appendix 7: **NWIHP/IOG CAG membership 2022**

Dr Cliona Murphy (Chair). Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Director, National Women and Infants Health Programme.

Dr Sam Coulter-Smith. Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Chair, Institute of Obstetricians and Gynaecologists.

Angela Dunne. Director of Midwifery, National Women and Infants Health Programme.

Kilian McGrane. Director, National Women and Infants Health Programme.

Dr Peter McKenna. Clinical Lead, Obstetric Event Support Team, National Women and Infants Health Programme.

Prof John Murphy. Clinical Lead Neonatology, National Women and Infants Health Programme.

Prof Maeve Eogan. Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Clinical Lead, Sexual Assault Treatment Units, National Women and Infants Health Programme.

Dr Aoife Mullaly. Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Lead, Termination of Pregnancy Services, National Women and Infants Health Programme.

Prof Keelin O'Donoghue. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Lead, National Guidelines, National Women and Infants Health Programme.

Prof Nóirín Russell. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, Cervical Check.

Prof Richard Greene. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, National Perinatal Epidemiology Centre, University College Cork.

Prof John Morrison. Consultant Obstetrician and Gynaecologist, University Hospital Galway. Clinical Director, Saolta Maternity Directorate.

Dr Suzanne O'Sullivan. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Director of Education and Training, Obstetrics and Gynaecology, Institute of Obstetricians and Gynaecologists.

Prof Fergal Malone. Master, Consultant Obstetrician and Gynaecologist, Rotunda Hospital.

Prof John Higgins. Cork University Maternity Hospital, Consultant Obstetrician and Gynaecologist, Clinical Director, Ireland South Women and Infants Directorate.

Dr Mendinaro Imcha. Clinical Director, Consultant Obstetrician and Gynaecologist, University Maternity Hospital Limerick.

Prof Shane Higgins. Master, Consultant Obstetrician and Gynaecologist, National Maternity Hospital.

Prof Mike O'Connell. Master, Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital.

Dr Brian Cleary. Chief Pharmacist, Rotunda Hospital. Medications Lead, Maternal and Newborn Clinical Management System Project.